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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM

Date: 15-SEP-2011

SUBJECT: **Novaluron.** Petition for the Establishment of Permanent Tolerances for Residues of Novaluron in/on Sweet Corn and All Food Commodities/Feed Commodities (Other Than Those Covered by a Higher Tolerance as a Result of Use on Growing Crops) in Food- or Feed-Handling Establishments. **Summary of Analytical Chemistry and Residue Data.**

PC Code: 124002
Decision Nos.: 432483; 430432
Petition Nos.: 0E7723; 0F7708
Risk Assessment Type: NA
TXR No.: NA
MRID Nos.: 48073501; 48034901-48034903

DP Barcodes: D378631; D378635
Registration Nos.: 66222-35; 66222-ERT
Regulatory Action: Amended Section 3
Case No.: 7615
CAS No.: 116714-46-6
40 CFR: §180.598

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THROUGH: George F. Kramer, Ph.D., Senior Chemist
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TO: Lata Venkateshwara, Risk Assessor
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And

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Registration Division (RD; 7505P)

And

John Hebert/Jennifer Gaines (RM 07)
RD (7505P)

Executive Summary

Novaluron, a benzoylphenyl urea compound, is a pesticide chemical belonging to the class of insecticides called insect-growth regulators (IGR). It is currently registered for use on various fruit and vegetable crops. The basic producer of novaluron is Makhteshim-Agan of North America (MANA). End-use products containing novaluron as the active ingredient (ai) are

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formulated as an emulsifiable concentrate (EC), a suspension concentrate (SC), or a water-dispersible granular (WDG).

Under PP#0E7723, the Interregional Research Project No. 4 (IR-4), on behalf of the Agricultural Experiment Station of Idaho, requests the establishment of permanent tolerances for residues of the insecticide novaluron in/on:

Corn, Sweet, Stover	50 ppm
Corn, Sweet, Forage	20 ppm
Corn, Sweet, Kernel Plus Cob With Husks Removed	0.05 ppm

IR-4 also proposed tolerance increases for residues of the insecticide novaluron, *N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide, in/on livestock commodities as follows:

Milk	1.5 ppm
Milk, Fat	35 ppm

Concurrently, under PP#0F7708, MANA requests the establishment of a permanent tolerances for residues of the insecticide novaluron, *N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide, in/on:

All food/feed items other than those covered by a higher tolerance as a result of use on growing crops	0.01 ppm

The end-use products associated with these registration requests are Rimon® 0.83EC Insecticide (EPA Reg. No. 66222-35) for use on sweet corn and Rimon® Supra 10EC Insecticide (EPA Est. No. 66222-ERT) for indoor and outdoor control of roaches and crickets. Both products are EC formulations which contain 9.3% ai by weight [equivalent to 0.83 pound (lb) ai/gallon (gal)]. The sweet corn label proposes a maximum seasonal Rimon® application rate of 0.39 lb ai/acre (A) (0.058 to 0.078 lb ai/A/application) with a 7-day retreatment interval (RTI) and a 1-day preharvest interval (PHI). The field trial data supports PHIs of 1 day for sweet corn stover, forage, and kernel plus cob with husks removed (K+CWHR), as well as the application rates for sweet corn as specified in the label. The food and feed handling use label proposes indoor use of a diluted spray (2.3–3.1 ounces per gallon of water) as a fogger, spot, crack and crevice, space spray, and general surface applications; however further clarification was provided by the registrant which stated that space or aerosol sprays, where a fogger or vaporizer are used, are not the intended application methods. The proposed outdoor use is a diluted spray (3.1 ounces per gallon of water) at a use rate of 1 gallon per 1,000 feet (1.2 ounces finished spray/yd^2).

A revised Section B for PP#0E7723 should be submitted which prohibits the use of novaluron on turnips harvested for the root and prohibits the feeding of turnip tops to livestock as requested in a previous HED memo (J. Van Alstine, 09-SEP-2009; D357060). This affects the current petition because it could result in increased livestock dietary burdens. A revised Section B is also requested for PP#0F7708 which removes all references to fogger and fog applications in the label and specifies that applications should be made with mechanical cold mist/ultra-low volume (ULV) equipment at an indoor application rate of 0.1 gallons per 1000 ft^2, which is supported by the food-handling establishment field trial. The revised Section B for PP#0F7708 should also state that all food processing surfaces (including equipment) and utensils should be covered

during treatment or thoroughly washed prior to use, and that livestock feed items should be removed or covered prior to application.

The nature of the residue in plants is understood based on acceptable plant metabolism studies reflecting foliar uses on apples, cabbage, cotton, and potatoes. The HED Metabolism Assessment Review Committee (MARC) concluded that the residue of concern in plants is novaluron only for tolerance enforcement and risk assessment purposes (Memo, G. Kramer *et al.*, 03-FEB-2004; D297646).

HED also previously concluded that the nature of the residue in livestock is adequately understood based on the submitted goat and hen metabolism studies (Memo, G. Kramer, 22-MAR-2004; D285474). The HED MARC determined that the residue of concern in livestock for purposes of tolerance enforcement and risk assessment is novaluron only (Memo, G. Kramer *et al.*, 03-FEB-2004; D297646).

The available confined rotational crop study is adequate. The HED MARC has determined that for tolerance assessment and risk assessment, parent only is the residue of concern (Memo, G. Kramer *et al.*, 03-FEB-2004; D297646). Based on the results of the confined rotational crop study, the appropriate plantback interval (PBI) for all non-labeled crops is 30 days. The current and proposed sweet corn label include a restriction that only registered crops may be rotated to a treated field within 30 days of the final application, which is appropriate for this petition.

There are adequate residue analytical methods for the enforcement of residue tolerances associated with these petitions. For novaluron residue analysis in crop matrices, gas chromatography/electron-capture detection (GC/ECD) and high-performance liquid chromatography/ultraviolet (HPLC/UV) methods are available. These methods have undergone successful validation by the Analytical Chemistry Branch of the Biological and Economics Analysis Division (ACB/BEAD) and have been forwarded to Food and Drug Administration (FDA) for inclusion in the Pesticide Analytical Method Volume II (PAM II; Memo, S. Levy, 15-SEP-2004; D307595).

Samples of sweet corn stover, forage, and K+CWHR from the field trials were analyzed for residues of novaluron using a GC/ECD method that is similar to the GC/ECD enforcement method. Acceptable method validation and concurrent method recovery data were submitted with the petition. Additionally, a liquid chromatography method with a tandem mass-spectrometric detection (LC/MS/MS) method, which is similar to the GC/ECD enforcement method, was used to analyze residues of novaluron in/on butter, meat, milk, bread, lettuce, and dinner plates in the food-handling establishment residue study. Acceptable concurrent method recovery data were submitted with the petition and a separate study was submitted which validated the method.

The requirements for Multiresidue Methods (MRMs) testing data for novaluron are fulfilled. The available data indicate that novaluron could not be recovered through application of the multiresidue protocols (Memo, S. Levy, 19-OCT-2005; D322359).

Concurrent storage stability data for sweet corn stover, forage, and K+CWHR were submitted. With the exception of two recoveries (125% and 138% in stover), all recoveries were within the acceptable 70–120% range; therefore, there are no concerns regarding the stability of residues of novaluron in/on K+CWHR, stover and forage matrices in the submitted study. An acceptable

storage stability study was submitted with the food-handling establishment study which demonstrates the storage stability of novaluron in/on butter, bread, lettuce, meat, milk, and dinner plates. Corrected recoveries ranged from 85-111%. Additionally, control samples were fortified with novaluron at the treatment facility (field fortified samples) and were stored for the same length of time as the field samples and indicated that residues of novaluron were stable during transport and storage.

Provided a revised Section B is submitted, the submitted field trial residue data for sweet corn stover, forage, and K+CWHR are adequate to support the establishment of the requested tolerances. Provided a revised Section B is submitted, the submitted food-handling establishment residue data are also adequate to support the establishment of the requested tolerance for food commodities/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments.

HED does not require residue data for any processed commodities associated with sweet corn. Therefore, data requirements for processed food and feed are not relevant to sweet corn commodities. Additionally, since the food- and feed-handling establishment label states that food items should be removed or covered prior to treatment and that packaged food items should be stored in such a way that direct contact with foodstuff is not anticipated, data requirements for processed food and feed are not relevant to this use pattern.

The field trial data sweet corn stover and forage were entered into the Agency's maximum residue limits (MRL) tolerance spreadsheet to determine appropriate tolerances. The tolerance spreadsheet was not used for sweet corn K+CWHR because all of the residues were less than the lowest level of method validation (LLMV; 0.05 ppm). The output from the tolerance spreadsheet and the submitted K+CWHR data support the IR-4 proposed tolerances of 50 ppm for residues in/on corn, sweet, stover and 0.05 ppm for corn, sweet, kernel plus cob with husks removed. The tolerance spreadsheet output did not support IR-4's proposal of 20 ppm for residues in/on corn, sweet, forage; the appropriate tolerance for corn, sweet, forage is 16 ppm. New reasonably balanced dietary burdens (RBDBs) were constructed based on the proposed new use on sweet corn; however new livestock tolerances are not required and the IR-4 proposed increases in milk and milk fat tolerances were not supported. Since the food and feed handling use label requires food to be covered or removed prior to application, and residues for all covered food matrices samples which were treated at a 3X application rate were below the limit of quantitation (LOQ; <0.010 ppm), except for one sample of bread collected 4 hours post-application, the recommended tolerance for all food/feed items other than those covered by a higher tolerance as a result of use on growing crops is 0.01 ppm.

No Codex, Canadian, or Mexican maximum residue limits (MRLs) have been established for novaluron in/on sweet corn stover, forage, and K+CWHR. Canada is currently in the process of reviewing the use of novaluron on sweet corn stover, forage, and K+CWHR. The EPA and the Pest Management Regulatory Agency (PMRA) tolerance recommendations have been harmonized at 0.05 ppm for sweet corn K+CWHR. The PMRA is also proposing an increase in its MRL for milk to 1.0 ppm from 0.5 ppm, and as a result, the EPA and PMRA milk tolerances/MRLs are now harmonized. The PMRA does not recommend MRLs for livestock feed commodities; therefore it is not possible to harmonize tolerances/MRLs for sweet corn stover and sweet corn forage. The PMRA has not received a petition for the use of novaluron in food and feed handling establishments; therefore, it is not possible to harmonize for the residues resulting from this proposed use.

Regulatory Recommendations and Residue Chemistry Deficiencies

Pending submission of revised Sections B and F and new analytical standards, there are no residue chemistry issues that would preclude granting an unconditional registration for the use of novaluron on sweet corn and in food and feed handling establishments where food or feed products are held, processed, or prepared.

The proposed uses and the submitted data support the permanent tolerances for residues of the insecticide novaluron, including its metabolites and degradates, in or on the commodities listed below. Compliance with the tolerance levels specified below is to be determined by measuring only novaluron (*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide) in or on the following raw agricultural commodities (RACs):

Corn, Sweet, Stover	50 ppm
Corn, Sweet, Forage	16 ppm
Corn, Sweet, Kernel Plus Cob With Husks Removed	0.05 ppm
Food/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments	0.01 ppm

A human-health risk assessment is forthcoming in a separate document (D377471; D378387). The residue chemistry database will support unconditional registration upon submission of data/information which adequately addresses the following issues:

860.1200 Directions for Use

A revised Section B for PP#0E7723 should be submitted which:

- prohibits the use of novaluron on turnips harvested for the root and prohibits the feeding of turnip tops to livestock as previously requested (Memo, J. Van Alstine, 09-SEP-2009; D357060). This affects the current petition because it could result in increased livestock dietary burdens.

A revised Section B for PP#0F7708 should be submitted which:

- specifies an application rate of 0.1 gallons per 1000 ft^2 for indoor spot, crack and crevice, space spray, and general surface applications;
- states that all food processing surfaces (including equipment) and utensils should be covered during treatment or thoroughly washed prior to use;
- states the livestock feed items should be removed or covered prior to application; and
- removes all references to fogger and fog applications in the label, and specifies that applications should be made with mechanical cold mist/ultra-low volume (ULV) equipment.

860.1550 Proposed Tolerances

A revised Section F for PP#0E7723 should be submitted which:

- cites the appropriate CAS name for novaluron:

"Tolerances are established for residues of the insecticide novaluron, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only novaluron (*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide) in or on the following raw agricultural commodities:"; and

- reflects the recommended tolerances and commodity definitions presented in Table 14.

Additionally, a revised Section F for PP#0F7708 should be submitted which:

- reflects the commodity definition presented in Table 14.

860.1650 Submittal of Analytical Reference Standards

The available analytical reference standards for novaluron have expired. MANA is required to submit an updated Certificate of Analysis (COA) or a new analytical standard to the EPA National Pesticide Standards Repository at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

Please note that the extended zip code is required for delivery.

Note to RD: Based on Chemistry Science Advisory Council (ChemSAC) guidance that meat byproduct tolerances should be set at the highest residue level seen in any livestock commodity (minutes from 12-JAN-2011), several meat byproduct tolerances in 40 CFR § 180.598(a) should be updated so that they are based on the highest expected residue. Additionally, two commodity descriptions should be updated. The tolerances and commodity descriptions should be updated as follows:

Current Commodity Description	Updated Commodity Description	Current Tolerance (ppm)	Updated Tolerance (ppm)[1]
Cattle, meat byproducts, except kidney and liver	-	0.60	11
Goat, meat byproducts except kidney and liver	-	0.60	11
Horse, meat byproducts, except kidney and liver	-	0.60	11
Sheep, meat byproducts, except kidney and liver	-	0.60	11
Hog, meat byproducts	Hog, meat byproducts, except kidney and liver[2]	0.10	1.5
Poultry, meat byproducts	Poultry, meat byproducts, except kidney and liver[3]	0.80	7.0

[1] Based on the based on the highest expected secondary tissue residue [peritoneal fat in cattle (translated to goat, horse, and sheep); peritoneal fat in hog; abdominal fat in poultry].
[2] Separate tolerances have been established for hog, kidney (0.10 ppm) and hog, liver (0.10 ppm).
[3] Separate tolerances have been established for poultry, kidney (0.80 ppm) and poultry, liver (0.80 ppm).

Background

The chemical structure and nomenclature of novaluron is listed in Table 1. The physicochemical properties of the technical grade of novaluron are presented in Table 2.

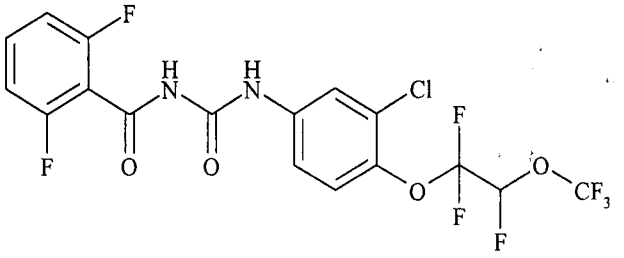
Table 1. Novaluron Nomenclature.	
Chemical structure	
Common name	Novaluron
IUPAC name	1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-3-[2,6-difluorobenzoyl]urea
CAS name	*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide
CAS registry number	116714-46-6
End-use products (EPs)	Rimon® 0.83EC Insecticide (0.83 lb/gal EC; EPA Reg. No. 66222-35); Rimon® Supra 10EC Insecticide (0.83 lb/gal EC; EPA Est. No. 66222-ERT)

Table 2. Physicochemical Properties of Technical Grade Novaluron.		
Parameter	Value	Reference
Melting range	176.5 - 178.0°C	DP# 315780, 3-NOV-2005, S. Levy
pH	6.5	
Density	1.56 g/cm^3 at 22°C	
Water solubility	3 µg/L at 20°C	
Solvent solubility (at 25°C)	0.00839 g/L in n-heptane 1.88 g/L in xylene 14.5 g/L in methanol 198 g/L in acetone 113 g/L in ethyl acetate 0.98 g/L in n-octanol	
Vapor pressure (mm Hg)	1.2 x 10^{-7}	
Dissociation constant, pK_a	Not determined due to low water solubility.	
Octanol/water partition coefficient, Log(K_{OW})	4.3 at 25°C	
UV/visible absorption spectrum	Molar absorption coefficients of at 3 maximum absorbances: 15,400 L/mol • cm at 253 nm (neutral) 9,780 L/mol • cm at 253 nm (acidic) 20,500 L/mol • cm at 263 nm (basic)	

860.1200 Directions for Use

IR-4 and MANA have submitted draft labels for Rimon® 0.83EC Insecticide (EPA Reg. No. 66222-35) and Rimon® Supra 10EC Insecticide (EPA Reg. No. 66222-ERT) to include the

proposed new uses (see Table 3) on sweet corn and in food and feed handling establishments. The current label for Rimon® Supra 10EC did not include an application rate for spot, crack and crevice, surface spray, and general surface applications; please refer to Appendix III for HED's application rate calculations.

Table 3. Summary of Directions for Use of Novaluron.

Applic. Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Sweet Corn (PP#0E7723)						
Aerial/ Ground-boom	0.83 lb/gal EC [66222-35]	0.058-0.078	5-6	0.39	1	Apply in sufficient volume to ensure full coverage of foliage and developing ears. Use higher rates and higher spray volumes when larvae are large or foliage canopy is tall or dense. The use of surfactants/adjuvants (including non-ionic surfactants) is prohibited. Repeat applications as needed to protect new growth, but not less than 7 days apart.
Residential and Commercial Buildings and Structures and Their Immediate Surroundings and on Modes of Transport[a] (PP#0F7708)						
Low-pressure handwand, trigger sprayer, ULV sprayer[c]	0.83 lb/gal EC [66222-ERT]	0.1 gal/1000 ft^2[b]	Not indicated	3.1 ounces per gallon of water = 0.02 lb ai/gal Spray rate per area: 0.1 gal/1000 ft^2 = 0.002 lb ai/1000 ft^2	NA	Prepare diluted spray solution by adding 2.3 to 3.1 ounces per gallon of water. Prior to application, remove or cover all food items in the area to be treated. *In the home*, all food-processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Do not replace food containers or foodstuffs until spray has dried. A retreatment interval (RTI) is not specified. The label states the product is effective for 180 days (26 weeks or 6 months).

[a] The permitted areas of use include non-food/non feed areas of stores; warehouses, transportation equipment, manufacturing sites, industrial buildings, houses, apartment buildings, office buildings, laboratories, schools, daycare centers, nursing homes, hospitals, hotels and on vessels, railcars, aircraft, buses, trucks, and trailers.

[b] The current label for Rimon® Supra 10EC did not include an application rate for spot, crack and crevice, surface spray, and general surface applications; please refer to Appendix III for HED's application rate calculations.

[c] Correspondence from MANA indicated that they do not intend to have a fogger use, but rather that applications should be made as a mechanical cold mist/ULV mist which targets the treatment spots. There are no unit exposures for this scenario but the available low-pressure handwand and trigger sprayer unit exposure data are protective of mechanical cold mist/ULV mist applications.

For ground applications to vegetables, a minimum spray volume of 10 gallons per acre (GPA) of Rimon® 0.83EC should be used. Aerial applications are to be made in 2-10 GPA. Applications

of Rimon® 0.83EC may also be made through sprinkler irrigation systems; use of other types of irrigation systems is prohibited. The accepted (master) label for Rimon® 0.83EC Insecticide states that only registered crops may be rotated in a treated field within 30 days of application. The current and proposed labels include a restriction that only registered crops may be rotated to a treated field within 30 days of the final application and to prohibit the use of novaluron on crops grown for food in greenhouses, except tomatoes. The current Section B for PP#0E7723 does not prohibit the use of novaluron on turnips harvested for the root or prohibit the feeding of turnip tops to livestock, as requested in a previous HED memo (J. Van Alstine, 09-SEP-2009; D357060). This affects the current petition because it could result in increased livestock dietary burdens.

Rimon® Supra 10EC is proposed for use in and around residential and commercial buildings and structures and their immediate surroundings and on modes of transport including: non-food/non-feed areas of stores; warehouses, transportation equipment, and manufacturing sites; industrial buildings; houses; apartment buildings; office buildings; laboratories; schools; daycare centers; nursing homes; hospitals; hotels; and on vessels, rail cars, aircraft, buses, trucks, and trailers. Fogger, spot, crack and crevice, space sprays, and general surface applications are specified in the label. In an email from B. Volger to J. Gaines (27-SEP-2010), the registrant stated:

> "[w]e do not intend to have a 'fogger' use registered. The application here is made with a mechanical cold mist/ULV equipment, such as ActisolR or Micro-injectorR that delivers a very light mist which targets the treatment spots to specific void areas (such as but not limited to wooden pallet structures, under sink/counter voids, under equipment, enclosed machinery housings etc.). With this application technique substantially less material is used than using a coarse fan, and allows the material to get to the insect colonies and resting places. There will be no filling the room with mist. It's not considered a space or aerosol spray, where a fogger or vaporizer is used, and the space is closed off for a certain period."

Conclusions: The proposed labels are adequate to allow evaluation of the residue data relative to the proposed new uses on sweet corn and in food- and feed-handling establishments; however a revised Section B for PP#0E7723 should be submitted which:

- prohibits the use of novaluron on turnips harvested for the root and prohibits the feeding of turnip tops to livestock as previously requested (Memo, J. Van Alstine, 09-SEP-2009; D357060). This affects the current petition because it could result in increased livestock dietary burdens.

Additionally, a revised Section B is requested for PP#0F7708 which:

- specifies an application rate of 0.1 gallons per 1000 ft^2 for indoor spot, crack and crevice, space spray, and general surface applications;
- states that all food processing surfaces (including equipment) and utensils should be covered during treatment or thoroughly washed prior to use;
- states the livestock feed items should be removed or covered prior to application; and
- removes all references to fogger and fog applications in the label, and specifies that applications should be made with mechanical cold mist/ultra-low volume (ULV) equipment.

860.1300 Nature of the Residue - Plants

MARC Decision Memo, DP# 297646, 2/3/04, G.F. Kramer
Residue Chemistry Memo, DP# 285474, 3/22/04, G.F. Kramer (PP#2F6430)

HED previously (PP#2F6430) concluded that the nature of the residue in plants is adequately understood based on acceptable metabolism studies conducted on apples, cabbage, cotton, and potatoes using [difluorophenyl-U-^{14}C]novaluron and [chlorophenyl-U-^{14}C]novaluron as the test substances (Memo, G. Kramer, 22-MAR-2004; D285474). These studies indicate that novaluron is not extensively metabolized in these crops. The parent compound, novaluron, was either the only residue component identified or was the predominant residue component in all analyzed plant matrices. The reviewed studies also indicate novaluron, when foliarly applied during the vegetative growth stage, is not readily translocated to mature apple fruit, potato tubers, or cottonseed (Memo, G. Kramer, 22-MAR-2004; D285474). The HED MARC determined that the residue of concern in crops for purposes of tolerance enforcement and risk assessment is novaluron only (Memo, G. Kramer *et al.*, 03-FEB-2004; D297646).

860.1300 Nature of the Residue - Livestock

HED also previously concluded that the nature of the residue in livestock is adequately understood based on the submitted goat and hen metabolism studies (Memo, G. Kramer, 22-MAR-2004; D285474). The HED MARC determined that the residue of concern in livestock for purposes of tolerance enforcement and risk assessment is novaluron only (Memo, G. Kramer *et al.*, 03-FEB-2004; D297646).

860.1340 Residue Analytical Methods

Residue Chemistry Memo, DP# 285474, 3/22/04, G.F. Kramer (PP#2F6430)
Residue Chemistry Memo, DP# 306998, 9/15/04, S. Levy (PMV Results)
Residue Chemistry Memo, DP# 307595, 9/15/04, S. Levy (PP#2F6430; Letter to FDA)
Residue Chemistry Memo, DP#s 322978 & 315780, 11/3/05, S. Levy (PP#4E6834)
Residue Chemistry Memo, DP# 325183, 8/23/06, S. Levy (PP#4E6834; Radiovalidation)

Enforcement Methods: MANA previously submitted under PP#2F6430 a GC/ECD residue analytical method for the analysis of residues of novaluron in/on pome fruit, cabbage, and potato commodities. Briefly, residues in/on homogenized crop samples are extracted with methanol (MeOH)/water. The filtered extracts are concentrated to aqueous and repeatedly partitioned with hexane. The resulting hexane fractions are cleaned up by chromatography through an amino solid-phase extraction (NH_2-SPE) cartridge, the eluate is evaporated to dryness, and residues are redissolved in ethyl acetate or hexane for analysis by GC/ECD. The validated LOQs are 0.01 ppm for residues in/on potatoes and 0.05 ppm for residues in/on apples (including juice and wet pomace) and cabbage.

A second method, HPLC/UV, was submitted for the analysis of novaluron residues only in/on cotton commodities. Similarly, samples are extracted with acetonitrile (ACN) or ACN/water, and repeatedly partitioned with hexane, or dichloromethane and then hexane. The resulting ACN fraction is cleaned up by gel-permeation chromatography (GPC), silica-gel chromatography, and/or NH_2-SPE for HPLC/UV analysis. The validated LOQ is 0.05 ppm for undelinted cottonseed, cotton gin byproducts, and the processed commodities of hulls, meal, and refined oil.

Successful independent laboratory validations (ILVs) of the GC/ECD and HPLC/UV methods have been completed with apples and undelinted cottonseed, respectively. Acceptable radiovalidation data have been submitted and reviewed in D325183 for the GC/ECD method. An interference study was requested and a specific single-analyte confirmatory method was submitted, reviewed, and considered acceptable (Memo, J. Langsdale, 21-OCT-2008; D355574).

The ACB concluded that based upon review of the submitted method validation data, without laboratory validation, that the GC/ECD and HPLC/UV methods appear suitable for food tolerance enforcement in plants (apples, cabbage, potatoes) and cotton. ACB recommended that the analytical methods do not need to be laboratory validated by EPA (Memo, S. Levy, 15-SEP-2004; DP306998). Both methods have been forwarded to the FDA for inclusion in the PAM II as a Letter Method (Letter, S. Levy to the Food and Drug Administration (FDA), 15-SEP-2004; D307595).

Sweet Corn Data-Collection Method: Residues of novaluron in treated sweet corn matrices were determined using a GC/ECD method based on the method entitled "Magnitude of the Residue of Novaluron in Pome Fruit Raw Agricultural and Processed Commodities" (MRID 45638420). A copy of this method was submitted with the field trial. The method used to analyze sweet corn has not been reviewed by the EPA, however the original method on which it is based (Method MAK 453/972510; MRID 45638304) has been reviewed and deemed acceptable by the Agency.

Briefly, samples were extracted with MeOH:water (70:30; v:v) twice, and the filtrates were combined. The volume was adjusted with 100% MeOH, aqueous (5%) NaCl and hexane were added, and the sample was partitioned. This step was repeated, and the combined hexane extracts were evaporated to a low volume using a rotary evaporator. The mixture was centrifuged, and the hexane layer was cleaned up on a NH_2-SPE cartridge, eluted with diethyl ether:ethyl acetate (50:50; v:v). The solvent was evaporated under nitrogen, and then residues were determined by GC/ECD. The LLMV was determined to be 0.05 ppm for corn K+CWHR, forage, and stover. The LOQ was determined to be 0.040 ppm, 0.052 ppm, and 0.049 ppm for K+CWHR, forage, and stover, respectively. The limit of detection (LOD) for the method was 0.013 ppm, 0.017 ppm, and 0.016 ppm for K+CWHR, forage, and stover, respectively.

The method was validated prior to sample analysis by spiking control K+CWHR, forage, and stover with 0.05 ppm, 0.5 ppm, and 5 ppm novaluron. Recoveries ranged from 83-116% (with standard deviations of 1-12%) in all matrices, indicated the method accurately determines residues of novaluron in K+CWHR, forage, and stover. To confirm analytical results from the field trials were reliable, control K+CWHR samples were spiked with 0.05 ppm, 0.5 ppm, and 5 ppm novaluron concurrently with the analytical sample sets. Additionally, forage samples were spiked with 0.05 ppm, 0.5 ppm, 5 ppm, and 25 ppm novaluron concurrently with the analytical sets. And, finally, control stover samples were spiked with 0.05 ppm, 0.5 ppm, 1 ppm, 5 ppm, and 60 ppm novaluron concurrently with the analytical sample sets. With the exception of one recovery (62% in stover sample spiked with 60 ppm novaluron), all concurrent recoveries fell within the acceptable 70-120% range, indicating the method is adequate for the determination of residues of novaluron in/on corn K+CWHR, forage, and stover in this study.

Food-Handling Establishment Data-Collection Method: Samples were analyzed based on the analytical methodology described in Protocol Amendment 1A to Landis International, Inc. Protocol Number 14521A008, entitled "Residue in Food Commodities Following Application of

a Liquid Formulation of Novaluron as a Space Spray Treatment in a Simulated Food Handling Establishment." The methods have not been reviewed by the EPA; however, the methods were based on previous food methodologies used to analyze residues of novaluron. Additionally, an acceptable study report entitled "Laboratory Validation of Methods for the Analysis of Novaluron in/on Butter, Processed Meat, Milk, White Bread, Lettuce, and Dinner Plate" (MRID 48034901) was submitted which validates the method.

Homogenized food matrices, except lettuce, were extracted with ACN (3 x 20 mL), cleaned up with hexane partitions (2 x 50 mL), concentrated using rotary evaporation with nitrogen, reconstituted in acetone with the aid of sonification, and filtered through a 0.45-μm polytetrafluoroethylene (PTFE) filter. Lettuce was first treated with methanol extraction (20 mL) followed by ACN extractions (2 x 20 mL) and the clean up, concentration and filtration steps described for the other food matrices. Aliquots of the filtered extracts were diluted with a solution of 50:50:0.1 (v/v/v) MeOH:H_2O:formic acid. For the dinner plates, the entire upper or eating surface was extracted using three washes of 10 mL acetone which were combined in a flask, evaporated, reconstituted, and diluted in the same manner as the food matrices less the filtration step. Residues were measured using LC/MS/MS in the negative-ion MRM mode. The LOQ was 0.01 ppm for all food commodities and 0.02 μg for dinner plates. LODs were not reported.

In conjunction with the food-handling trial, the method was concurrently validated using control samples of butter fortified with novaluron at 0.010-2.0 ppm; turkey meat fortified at 0.010-3.5 ppm; milk fortified at 0.010-1.0 ppm; bread fortified at 0.010-15.0 ppm; lettuce fortified at 0.010-3.0 ppm; and dinner plates fortified at 0.020-1200 μg. All recoveries but one (133% recovery for dinner plates fortified at 0.020 μg) were between the acceptable range of 70-120% and all mean recoveries were within the acceptable range.

Conclusions: HED previously concluded that the submitted GC/ECD method is adequate as an enforcement method for novaluron, the terminal residue of concern in plants (apple, cabbage, cotton, and potato). The enforcement method, with minor modifications, was used for data collection and the method was adequately validated in conjunction with the sweet corn field trials. The appropriate enforcement method for food- and feed-handling establishments is Method 243C-106 (MRID 48034901), which was used for data collection for the food-handling establishment field trial and was adequately validated.

860.1360 Multiresidue Methods

Residue Chemistry Memo, DP# 322359, 10/19/2005, S. Levy (PP#2F6430)

Novaluron was tested through the FDA MRM Test guidelines in PAM I, Appendix II (JAN-1994). The results indicate that novaluron is not adequately recovered by any of the MRMs. This study was forwarded to FDA for further evaluation and updating of PAM Vol. I, Appendix I.

860.1380 Storage Stability

Residue Chemistry Memo, DP# 285474, 22-MAR-04, G.F. Kramer (PP#2F6430)
Residue Chemistry Memo, DP# 357060, 09-SEP-2009, J.L. Van Alstine (PP#8E7425)
Residue Chemistry Memo, DP# 364237, 04-DEC-2009, J.L. Van Alstine (PP#9E7546)

Storage stability data for novaluron were previously presented in PP#2F6430. These data show that fortified residues of novaluron are reasonably stable under frozen conditions in/on pears for up to 5.2 months; broccoli, cabbage, and tomato for up to 6 months; apple and potato for up to 12 months; and apple juice for up to 3.3 months. Concurrent storage stability data was submitted for blueberries, mustard greens, and peaches in PP#8E7425, which demonstrated that fortified residues of novaluron are relatively stable under frozen conditions in/on blueberry, mustard greens, and peaches for up to 4.9 months, 15.3 months, and 3.8 months, respectively. Storage stability data have also been submitted which demonstrate that fortified residues of novaluron are relatively stable under frozen conditions in/on bell pepper for 6.7 months, cantaloupe for 7.0 months, summer squash for 9.4 months, strawberry for 11.7 months, snap bean pods with seeds for 8.6 months, snap bean foliage for 8.7 months, dry bean seed for 5.0 months, and Swiss chard for 11.7 months.

A storage stability study was conducted concurrently with the analytical portion of the residue sweet corn field trial study. Treated K+CWHR, forage, and stover were stored frozen (<-20°C) from harvest to extraction for a maximum of 785 days, 795 days, and 791 days (~ 26 months), respectively. Untreated control K+CWHR, forage, and stover samples from the Salisbury, MD trial (MD17) were spiked with 0.5 ppm novaluron, and stored frozen for 763 days, 775 days, and 777 days, respectively. Recoveries in spiked K+CWHR, forage, and stover samples ranged from 95-118% (n = 3), from 96-119% (n = 3), and from 109-138% (n = 3), respectively. The study indicated that concurrent recoveries ranged from 100-120%, but did not give individual recoveries. With the exception of two recoveries (125% and 138% in stover), all recoveries were within the acceptable 70-120% range, therefore, there are no concerns regarding the stability of residues of novaluron in/on K+CWHR, stover and forage matrices in this study.

Table 4. Summary of Storage Conditions and Durations of Samples from Sweet Corn Crop Field Trials.

Matrix (RAC)	Storage Temperature(°C)	Actual Storage Duration (days)[1]	Interval of Demonstrated Storage Stability(days)
K+CWHR[2]	<-20	785	A storage stability study was conducted concurrently with the analytical portion of the residue field trial study. Untreated control K+CWHR, forage, and stover samples from the Salisbury, MD trial (MD17) were spiked with 0.5 ppm novaluron, and stored frozen for 763 days, 775 days, and 777 days, respectively. Recoveries in spiked K+CWHR, forage, and stover samples ranged from 95 – 118 % (n = 3), from 96-119% (n = 3), and from 109-138% (n = 3), respectively. The study indicated that concurrent recoveries ranged from 100-120%, but did not give individual recoveries. With the exception of two recoveries (125% and 138% in stover), all recoveries were within the acceptable 70-120% range; therefore, there are no concerns regarding the stability of residues of novaluron in/on K+CWHR, stover and forage matrices in this study.
Forage		795	
Stover		791	

[1] From harvest to extraction. Samples were analyzed within 11 days of extraction.
[2] K+CWHR = kernels plus cob with husk removed.

An acceptable storage stability study (MRID 48034902) was submitted with the food-handling establishment study which demonstrates the storage stability of novaluron in/on butter, bread, and lettuce for up to 70 days; in/on meat for up to 71 days; and in/on milk and dinner plates for up to 92 days. Food matrices were fortified with novaluron at 0.100 ppm and dinner plates were fortified at 0.200 µg. Corrected recoveries ranged from 85-111% and were within the acceptable 70-120% range, therefore, there are no concerns regarding the stability of residues of novaluron

in/on butter, meat, milk, bread, lettuce and dinner plate matrices in this study.

Additionally, control samples were fortified with novaluron at the treatment facility (field fortified samples) at 0.100 ppm and 0.200 ppm for food matrices and 0.200 µg and 0.400 µg for dinner plates. These field fortified samples were stored for the same length of time as the field samples and indicate that residues of novaluron were stable during transport and storage. With the exception of two recoveries (62% and 154% in lettuce fortified at 0.100 ppm), all recoveries were between the acceptable range of 70-120% and all mean recoveries were within the acceptable range.

Table 5. Summary of Storage Conditions and Durations from Food-Handling Establishment Trials.

Matrix (Description)	Storage Temperature (°C)[1]	Actual Storage Duration (days and months)[2]	Interval of Demonstrated Storage Stability (days or months)[3]
Butter (Salted sweet cream butter)	-18	49 days (1.6 months)	70 days (2.3 months)
Meat (Roasted white turkey meat)		43 days (1.4 months)	71 days (2.3 months)
Milk (Vitamin D whole milk)		77 days (2.5 months)	92 days (3.0 months)
Bread (Whitewheat® bread)		69 days (2.3 months)	70 days (2.3 months)
Lettuce (Iceberg head lettuce)		63 days (2.1 months)	70 days (2.3 months)
Dinner plates (Glazed, vitreous china plate)		82 days (2.7 months)	92 days (3.0 months)

[1] Storage temperatures at the analytical facility. Samples were stored in the field at -21 to 15 °F.
[2] Elapsed days from sampling to extraction. All samples were analyzed within 4 days of extraction.
[3] Wildlife International Study 234C-107 (MRID 48034902).

Conclusions: The storage stability data for sweet corn are considered scientifically acceptable. With the exception of two recoveries (125% and 138% in stover), all recoveries from the concurrent storage stability study were within the acceptable 70-120% range, therefore, there are no concerns regarding the stability of residues of novaluron in/on K+CWHR, stover and forage matrices in this study. The storage stability data for butter, meat, milk, bread, lettuce, and dinner plate matrices are also considered scientifically acceptable. Corrected recoveries ranged from 85-111% and were within the acceptable 70-120% range; therefore, there are no concerns regarding the stability of residues of novaluron in/on butter, meat, milk, bread, lettuce and dinner plate matrices in this study. Additionally, with the exception of two recoveries (62% and 154% in lettuce fortified at 0.100 ppm), all recoveries for the field fortified samples were between the acceptable range of 70-120% and all mean recoveries were within the acceptable range.

860.1480 Meat, Milk, Poultry, and Eggs

Livestock dietary burdens

Residue Chemistry Memo, DP# 285474, 3/22/2004, G.F. Kramer (PP#2F6430)
Residue Chemistry Memo, DP# 315890, 5/10/2005, G.F. Kramer (PP#2F6430)
Residue Chemistry Memo, DP# 336897, 1/31/2008, S. J. Levy (PP#2F06430)
Residue Chemistry Memo, DP# 340137, 2/07/2008, G.F. Kramer (PP# 7E7199)

The potential for secondary transfer of novaluron residues of concern in meat, milk, and eggs exists because there are livestock feedstuffs associated with the proposed/registered novaluron uses. The livestock dietary burdens of novaluron are presented in Table 6 and reflect the most recent guidance from HED (Table 1, 6/08) concerning revisions of feedstuff percentages and constructing RBDBs.

Table 6. Calculation of Dietary Burdens of Novaluron Residues to Livestock[1].					
Feedstuff	Type[2]	% Dry Matter[3]	% Diet[3]	Recommended Tolerance (ppm)	Dietary Contribution (ppm)[4]
Beef Cattle: 15% R, 80% CC, 5% PC					
Sorghum, grain, stover	R	88	15	40.0	6.82
Sorghum, grain, grain	CC	86	35	3.0	1.22
Sugarcane, molasses	CC	75	5	0.5	0.033
Grains, aspirated fractions	CC	85	5	25	1.47
Untreated	CC	--	35	--	--
Cottonseed, meal	PC	89	5	0.60	0.034
TOTAL BURDEN	--	--	100	--	**9.6**
Dairy Cattle[5]: 45% R, 45% CC, 10% PC					
Corn, sweet, forage	R	48	45	16	15.0
Sorghum, grain, grain	CC	86	35	3.0	1.22
Apple, wet pomace	CC	40	10	8.0	2.0
Cotton, undelinted seed	PC	88	10	0.60	0.068
TOTAL BURDEN	--	--	100	--	**18.3**
Poultry: 75% CC, 25% PC					
Sorghum, grain, grain	CC	86	75	3.0	2.25
Cottonseed, meal	PC	89	20	0.60	0.12
Cowpea, seed	PC	88	5	0.3	0.02
TOTAL BURDEN	--	--	100	--	**2.4**
Swine: 85% CC, 15% PC					
Sorghum, grain, grain	CC	86	80	3.0	2.4
Untreated	CC	--	5	--	--
Cottonseed, meal	PC	89	15	0.60	0.09
TOTAL BURDEN	--	--	100	--	**2.5**

[1] Table prepared by Jerry Stokes; 23-NOV-2010.
[2] R: roughage; CC: carbohydrate concentrate; PC: protein concentrate.
[3] OPPTS 860.1000 Table 1 Feedstuffs (June 2008).
[4] Contribution = ([tolerance /% DM] X % diet) for beef and dairy cattle; contribution = ([tolerance] X % diet) for poultry and swine.
[5] PP#8E7425 (Memo, J. Van Alstine, 09-SEP-2009; D357060) included a request for the use of novaluron on turnip greens; HED requested that the petitioner submit a new label which prohibits the use of novaluron on turnips harvested for the root and prohibits the feeding of turnip tops to livestock.

Expected secondary residues in ruminant meat and milk

To determine the need for revisions to the tolerances for novaluron residues of concern in milk and tissues, the anticipated secondary residues in cattle matrices were estimated using average transfer coefficients calculated from the maximum residues of novaluron observed at the 3.9-, 12.6-, and 42.8-ppm dose levels (PP#2F6430). The transfer coefficients (calculated as residue-level-to-feed ratios) are presented in Table 7. The transfer coefficient for each matrix was then used to calculate the expected secondary residues by multiplying the average transfer coefficient by the calculated dietary burden (Tables 8 and 9).

Table 7. Residue-Level-to-Feed Ratios (Transfer Coefficients) in Dairy Cattle Milk and Tissues.			
Matrix	Maximum Residues (ppm)	Feeding Levels (ppm)	Transfer Coefficients (Average)
Whole milk	0.17, 0.43, 2.07	3.9, 12.6, 42.8	0.044, 0.034, 0.048, (0.042)
Muscle	0.09, 0.34, 0.56		0.023, 0.027, 0.013, (0.021)
Kidney	0.14, 0.35, 1.20		0.036, 0.028, 0.028, (0.031)
Liver	0.14, 0.41, 1.36		0.036, 0.033, 0.032, (0.034)
Fat (peritoneal)	2.25, 6.83, 12.89		0.577, 0.542, 0.301, (0.473)

Table 8. Expected Secondary Residues in Cattle Meat and Milk.				
Matrix	Dietary burden (ppm)	Secondary Residues (ppm)[1]	Established Tolerance (ppm)	Recommended Tolerance (ppm)
Whole milk	18.3	0.77	1.0	1.0
Muscle		0.39	0.60	0.60
Kidney		0.56	1.0	1.0
Liver		0.61	1.0	1.0
Fat (peritoneal)		8.7	11	11

[1] Calculated from dietary burden x average transfer coefficient from Table 7.

Table 9. Expected Secondary Residues in Hog Meat.				
Matrix	Dietary burden (ppm)	Secondary Residues (ppm)[1]	Established Tolerance (ppm)	Recommended Tolerance (ppm)
Muscle	2.5	0.05	0.07	0.07
Kidney		0.08	0.10	0.10
Liver		0.08	0.10	0.10
Fat (peritoneal)		1.2	1.5	1.5

[1] Calculated from dietary burden x average transfer coefficient from Table 7.

Expected secondary residues in poultry meat and eggs

To determine the need for tolerances for novaluron residues of concern in poultry meat and eggs, the anticipated secondary residues in poultry matrices were estimated using average transfer coefficients calculated from the maximum residues of novaluron observed in the hen metabolism study (0.12-, 0.36-, 1.2-ppm dose levels; PP#2F06430). The transfer coefficients (calculated as residue-level-to-feed ratios) are presented in Table 10. The transfer coefficient for each matrix was then used to calculate the expected secondary residues by multiplying the average transfer coefficient by the calculated dietary burden (Table 11).

Table 10. Residue-Level-to-Feed Ratios (Transfer Coefficients) in Poultry Eggs and Tissues.			
Matrix	Maximum Residues (ppm)	Feeding Levels (ppm)	Transfer Coefficients (Average)
Eggs (day 54)	0.063, 0.181, 0.702	0.12, 0.36, 1.2	0.52, 0.50, 0.58, (0.54)
Muscle	0.014, 0.031, 0.160		0.12, 0.086, 0.13, (0.11)
Liver	0.034, 0.096, 0.364		0.28, 0.27, 0.30, (0.28)
Kidney	0.039, 0.089, 0.368		0.32, 0.25, 0.31, (0.29)
Fat (abdominal)	0.323, 0.988, 3.011		2.7, 2.7, 2.5, (2.6)

Table 11. Expected Secondary Residues in Poultry Meat and Eggs.				
Matrix	Dietary burden (ppm)	Secondary Residues (ppm)[1]	Established Tolerance (ppm)	Recommended Tolerance (ppm)
Eggs (day 54)	2.4	1.3	1.5	1.5
Muscle		0.27	0.40	0.40
Liver		0.68	0.80	0.80
Kidney		0.70	0.80	0.80
Fat (abdominal)		6.4	7.0	7.0

[1] Calculated from dietary burden x average transfer coefficient from Table 10.

Conclusions: The currently established livestock tolerances are based on the following RBDBs for novaluron: 16.9 ppm for beef cattle and 11.9 ppm for dairy cattle (Memo G. Kramer, 22-MAR-2004; D285474) and 2.4 ppm for poultry and 2.5 ppm for swine (Memo, J. Van Alstine, 23-FEB-2010; D374420). Based on the proposed/registered uses, the revised RBDBs for novaluron are 9.6 ppm for beef cattle, 18.3 ppm for dairy cattle, 2.4 for poultry, and 2.5 for swine. No changes are necessary for the tolerances for secondary residues in/on cattle, goat, horse, sheep, poultry, and swine commodities. Although IR-4 requested increasing tolerances for residues of novaluron in milk from 1.0 to 1.5 ppm and milk, fat from 20 to 35 ppm, increased tolerances are not required for these commodities at this time. IR-4 is requested to submit a revised Section F which removes the proposed changes to milk and milk fat tolerances. Additionally, based on ChemSAC guidance that meat byproduct tolerances should be set at the highest residue level seen in any livestock commodity (minutes from 12-JAN-2011), several meat byproduct tolerances in 40 CFR § 180.598(a) should be updated so that they are based on the highest expected residue. Two commodity descriptions should also be updated. The tolerances and commodity descriptions should be updated as outlined in Table 15.

860.1500 Crop Field Trials

Sweet Corn

DER Reference: 48073501.der.doc

Fourteen residue trials were conducted in the US and Canada in the 2007 growing season in Zone 1 (1 in NY), Zone 2 (1 in NJ; 1 in MD), Zone 3 (1 in FL), Zone 5 (2 in ND; 2 in ON), Zone 5A (1 in WI; 1 in MI), Zone 7A (1 in AB), Zone 10 (1 in CA), Zone 11 (1 in WA), and Zone 12 (1 in OR).

Novaluron was applied to sweet corn using an EC formulation (Rimon® 0.83EC), as 5 directed or broadcast foliar applications, at rates of 0.077-0.088 lb ai/A, at RTIs of 5-8 days, for total rates of 0.389-0.424 lb ai/A. There were no adjuvants included in any of the spray mixtures. Commercially mature sweet corn K+CWHR, forage, and stover were harvested at a 1-day PHI, and additional samples were harvested at PHIs of 0, 2, 7, and 9 days at one trial site (MI17) to examine residue decline behavior.

Residues of novaluron in treated K+CWHR samples were all <0.05 ppm when treated with 5 foliar applications of novaluron at total rates of 0.389-0.424 lb ai/A, when samples were harvested at a 1-day PHI. Residues of novaluron in treated sweet corn forage and stover ranged from 0.35-14.13 ppm, and from 0.43-52.06 ppm, respectively, when treated at the same rates and

harvested at a 1-day PHI. Residues of novaluron appeared to increase with increasing PHI in both sweet corn forage and stover when harvested at PHIs of 0, 1, 2, 7, and 9 days. Residues of novaluron in K+CWHR were all <0.05 ppm when harvested at PHIs of 0, 1, 2, 7, and 9 days.

Table 12. Summary of Residue Data from Crop Field Trials with Novaluron (Sweet Corn).

Commodity	Total Applic. Rate g ai/ha [lb ai/A]	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT[1]	Median	Mean	Std. Dev.
K+CWHR	436-475 [0.389-0.424]	1	28	<0.05	<0.05	<0.05	<0.05	<0.05	0
Forage			28	0.35	14.13	11.52	4.24	5.19	3.58
Stover			28	0.43	52.06	48.52	12.98	12.99	11.77

[1] HAFT = highest-average field trial.

Conclusions: The number and locations of field trials are in accordance with OPPTS Guideline 860.1500 for sweet corn. The field trial data reflect the proposed use rate and PHI for sweet corn.

The field trial data for sweet corn stover and forage were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data Standard Operating Procedure (SOP)* to determine appropriate tolerance levels; see Appendix II. All residues in/on K+CWHR were less than the LLMV (0.05 ppm); therefore, the recommended tolerance for sweet corn K+CWHR is 0.05 ppm. The available data support tolerances of 50 ppm, 16 ppm, and 0.05 ppm for residues of novaluron in/on sweet corn sweet corn stover, forage, and K+CWHR, respectively.

Food-Handling Establishments

DER Reference: 48034901.der.doc

A residue study was conducted for a simulated food-handling establishment by Landis International, Inc. A space spray treatment of Diamond® 0.83 EC, containing 0.83 lb ai/gal novaluron, in the form of a fine mist (i.e., fog) was made at an application rate of 38.75 mg ai/m^2 (target rate of 25 mg/m^2) which was stated to be 3X the label rate. This type of application represents a worst-case scenario. The treated room contained three tables with randomly placed test matrices, including butter, sliced turkey meat, whole milk, sliced white bread, iceberg head lettuce, and bare plates. A subset of the matrices sampled was covered with thin plastic wrap to simulate typical storage conditions in a food-handling establishment. Uncovered treated samples were collected at sampling intervals of 4, 8, and 12 hours post-application, while covered treated samples were collected at 4 and 12 hours. Additional uncovered samples were placed in the rooms 2 hours after the spray application and collected at the same time as the 4- and 12-hour samples to evaluate deposition due to test substance volatilization. An untreated room was established as a control in a separate building. Untreated samples were collected 1 hour prior to treatment and 12 hours post-treatment.

Following a single treatment of novaluron at a rate of 38.75 mg ai/m^2, residues on uncovered sample matrices ranged from 0.140 to 1.12 ppm in/on butter (maximum at 4 hours); 0.0111 to 3.31 ppm in/on meat (maximum at 8 hours); 0.250 to 0.620 ppm in/on milk (maximum at 12 hours); 2.47 to 10.1 ppm in/on bread (maximum at 12 hours); 0.316 to 2.29 ppm in/on lettuce (maximum at 4 hours); and 784 to 1088 µg for dinner plates (maximum at 8 hours). For

uncovered butter and lettuce, residue concentrations of novaluron decreased by the end of the sampling period, while concentrations in/on uncovered meat, milk, bread, and dinner plates increased slightly over time.

Residues for all covered food matrices samples were <LOQ (<0.010 ppm), except for one sample of bread collected 4 hours post-application (0.0142 ppm). Residues on covered dinner plates ranged from 0.318 to 1.51 µg with the maximum occurring at 4 hours post-application.

All volatilization food samples, placed in rooms 2 hours after the spray application, were <LOQ (<0.010 ppm). Dinner plates placed in the room at 2 hours post-application had measured novaluron residues ranging from 0.905 to 1.03 µg.

With the exception of one +12 hour replicate in the butter matrix (0.00176 ppm), novaluron was not detected in any of the control food or dinner plate samples.

Table 13. Summary of Residue Data from Food-Handling Establishment Studies with Novaluron.

Commodity	Total Applic. Rate mg ai/m^2	Method/ Transfer Route	Residue Levels[1] (ppm)						
			n	Min.	Max.	HAFT[2]	Median	Mean	Std. Dev.
Butter, uncovered	38.75	Air	9	0.140	1.12	0.888	0.716	0.714	0.311
Butter, covered			6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Meat, uncovered	38.75	Air	9	0.0111	3.31	2.85	2.29	2.09	0.985
Meat, covered			6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Milk, uncovered	38.75	Air	9	0.250	0.620	0.412	0.343	0.397	0.136
Milk, covered			6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Bread, uncovered	38.75	Air	9	2.47	10.10	5.63	4.06	4.31	2.29
Bread, covered			6	<LOQ	0.0142	0.0114	0.0100	0.0107	0.00171
Lettuce, uncovered	38.75	Air	9	0.316	2.29	1.78	1.67	1.58	0.578
Lettuce, covered			6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Dinner plates, uncovered	38.75	Air	9	784 µg	1088 µg	1022 µg	921 µg	950 µg	112 µg
Dinner plates, covered			6	0.318 µg	1.51 µg	0.890 µg	0.580 µg	0.711 µg	0.424 µg

[1] The LOQ is 0.01 ppm for all food matrices and 0.02 µg for dinner plates. For the median, mean, and standard deviation, the LOQ was used for residues reported as below the LOQ. Units for food matrices are ppm and units for dinner plates are µg.
[2] HAFT = highest-average field trial.

Conclusions: The food-handling study is adequate and reflects the use of novaluron as a space spray treatment to a simulated commercial food establishment at a rate of 38.75 mg ai/m^2 (3X application rate), with a product application rate of 0.1 gal/1000 ft^2 (see Appendix III for calculations). An exaggerated rate was used to generate worst-case residues. The residues for all covered food matrices samples treated at a 3X application rate were <LOQ (<0.010 ppm)

except for one sample of bread (0.0142 ppm) collected 4 hours post-application. HED does not expect residues to be higher than 0.01 ppm in covered food and feed items following treatment at a 1X application rate because 29 out of 30 measured residues were below the LOQ, even when treated at a 3X rate, and the food-handling establishment label states that food items should be removed or covered prior to treatment and that packaged food items should be stored in such a way that direct contact with foodstuff is not anticipated. The available data support the proposed tolerance of 0.01 ppm for residues in/on food/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food- and feed-handling establishments.

860.1520 Processed Food and Feed

HED does not require residue data for any processed commodities associated with sweet corn. Therefore, data requirements for processed food and feed are not relevant to sweet corn commodities. Additionally, since the food and feed handling establishment label states that food items should be removed or covered prior to treatment and that packaged food items should be stored in such a way that direct contact with foodstuff is not anticipated, data requirements for processed food and feed are not relevant to this use pattern.

860.1650 Submittal of Analytical Reference Standards

The available analytical reference standards for novaluron expired on 22-NOV-2010 (personal communication with Theresa Cole, 22-NOV-2010). MANA is required to submit an updated COA or a new analytical standard to the EPA National Pesticide Standards Repository at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

Please note that the extended zip code is required for delivery.

860.1850 and 860.1900 Confined and Field Accumulation in Rotational Crops

The sweet corn commodities associated with the current petitions may be rotated. The available confined rotational crop study is adequate (Memo, G. Kramer, 22-MAR-2004; D285474). In the submitted confined rotational crop study, the application rate (~0.089 lb ai/A) of the test substance was equivalent to 0.3X the maximum proposed seasonal rate of application (0.27 lb ai/A) for cotton and potatoes. HED generally requires that the confined rotational crop study be conducted at 1.0X the proposed maximum seasonal rate for annual crops (or crops which can be rotated). However, as the total radioactive residue (TRR) was <0.005 ppm in all of the rotated crop commodities, it is unlikely that significant residues would be present at 1X. Future uses that have significantly higher application rates will require confined rotational crop studies at higher rates using chlorophenyl-labeled novaluron. Based on the results of the confined rotational crop study, the appropriate PBI for all non-labeled crops is 30 days (Memo, G. Kramer, 22-MAR-2004; D285474). The current and proposed labels include a restriction that only registered crops may be rotated to a treated field within 30 days of the final application. The HED MARC has determined that for tolerance assessment and risk assessment, parent only is the residue of concern (Memo, G. Kramer *et al.*, 03-FEB-2004; D297646).

An additional field rotational crop study was submitted and considered incomplete because certain rotational crop commodities (turnip tops and wheat forage, hay, and grain) were not analyzed or included in the study and crops were planted at only one location (Memo, G. Kramer, 07-FEB-08; D379033). Although incomplete, the data did demonstrate that it is unlikely that residues of novaluron would accumulate at ≥0.05 ppm (LOQ) in/on rotated turnip roots and wheat straw planted ~30, 60, or 90 days following treatment of primary crops at 0.9-1X the maximum seasonal rate. No additional field rotational crop data will be required as the current and proposed labels include a restriction that only registered crops may be rotated to a treated field within 30 days of the final application.

860.1550 Proposed Tolerances

HED has determined that the residue of concern in plants for tolerance enforcement is novaluron only. A summary of HED's recommended tolerances for the current petition are listed in Table 14. Revised Section Fs are requested which reflect HED's recommended tolerances and commodity definitions presented in Table 14.

No Codex, Canadian, or Mexican MRLs have been established for novaluron in/on sweet corn stover, forage, and K+CWHR. Canada is currently in the process of reviewing the use of novaluron on sweet corn stover, forage, and K+CWHR. The EPA and PMRA tolerance recommendations have been harmonized at 0.05 ppm for sweet corn K+CWHR. The PMRA is also proposing an increase in its MRL for milk to 1.0 ppm from 0.5 ppm, and as a result, the EPA and PMRA milk tolerances/MRLs are now harmonized. The PMRA does not recommend MRLs for livestock feed commodities; therefore it is not possible to harmonize tolerances/MRLs for sweet corn stover and sweet corn forage. The PMRA has not received a petition for the use of novaluron in food and feed handling establishments; therefore, it is not possible to harmonize for the residues resulting from this proposed use.

The Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was utilized for determining appropriate tolerance levels; see Appendix II for tolerance calculations.

Table 14. Tolerance Summary for Novaluron.

Commodity	Proposed Tolerance (ppm)	HED-Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Corn, Sweet, Stover	50	50	*Corn, sweet, stover*
Corn, Sweet, Forage	20	16	*Corn, sweet, forage*
Corn, Sweet, Kernel Plus Cob With Husks Removed	0.05	0.05	*Corn, sweet, kernel plus cob with husks removed*
Milk	1.5	1.0	An increase in the tolerance for residues of novaluron in milk is not needed at this time.
Milk, fat	35	20	An increase in the tolerance for residues of novaluron in milk fat is not needed at this time.
All food/feed items other than those covered by a higher tolerance as a result of use on growing crops	0.01	0.01	*Food/feed commodities (other than those covered by a higher tolerance as a result of use on growing crops) in food/feed handling establishments*

Note to RD: Based on ChemSAC guidance that meat byproduct tolerances should be set at the highest residue level seen in any livestock commodity (minutes from 12-JAN-2011), several meat byproduct tolerances in 40 CFR § 180.598(a) should be updated so that they are based on the highest expected residue. Additionally, two commodity descriptions should be updated. The tolerances and commodity descriptions should be updated as outlined in Table 15.

Table 15. HED-Proposed Updates to 40 CFR § 180.598 (a) Based on 12-JAN-2011 ChemSAC Minutes.

Current Commodity Definition	Updated Commodity Description	Current Tolerance (ppm)	Updated Tolerance (ppm)[1]
Cattle, meat byproducts, except kidney and liver	-	0.60	11
Goat, meat byproducts except kidney and liver	-	0.60	11
Horse, meat byproducts, except kidney and liver	-	0.60	11
Sheep, meat byproducts, except kidney and liver	-	0.60	11
Hog, meat byproducts	Hog, meat byproducts, except kidney and liver[2]	0.10	1.5
Poultry, meat byproducts	Poultry, meat byproducts, except kidney and liver[3]	0.80	7.0

[1] Based on the based on the highest expected secondary tissue residue [peritoneal fat in cattle (translated to goat, horse, and sheep); peritoneal fat in hog; abdominal fat in poultry].
[2] Separate tolerances have been established for hog, kidney (0.10 ppm) and hog, liver (0.10 ppm).
[3] Separate tolerances have been established for poultry, kidney (0.80 ppm) and poultry, liver (0.80 ppm).

References

MARC Decision Memo, DP# 297646, 2/3/04, G.F. Kramer

DP#: 307595
Subject: PP#2F6430. Memo to FDA for Inclusion of the Novaluron Analytical Methods in PAM Vol II as a Letter Method.
From: S. Levy
To: M. Wirtz (FDA)
Date: 09/15/04

DP#s: 285474, 287627, 297094, 297228 & 298477
Subject: PP#2F06430. Novaluron. Petition for the Establishment of Permanent Tolerances for Use on Cotton, Pome Fruits, and Potato. Summary of Analytical Chemistry and Residue Data.
From: G. Kramer
Date: 3/22/04

DP#: 306998
Subject: PP#2F6430. Novaluron in/on Cotton, Pome Fruit, and Potato. Results of the Petition Method Validation (PMV) of the Proposed Analytical Enforcement Methods for Plant and Livestock Raw Agricultural Commodities (RACs).

From: S. Levy
Date: 09/15/04

DP#: 315890
Subject: PP#2F06430. Novaluron on Cotton, Pome Fruits, and Potato. Review of Amendment Dated 9/28/04 Submitted in Response to HED's Memo of 3/22/04. Submission of Additional Information for the Dairy Cattle Feeding Study.

From: G. Kramer
Date: 5/10/05
MRIDs: 46374101

DP#s: 322978 & 315780
Subject: Novaluron. Petitions for the Establishment of Permanent Tolerances for Use on *Brassica*, head and stem, subgroup 5A (PP#4E6834) and Label Amendment for New Use on Pome Fruit (PP#2F6430). Summary of Analytical Chemistry and Residue Data.

From: S. Levy
Date: 11/3/05

DP#: 325183
Subject: PP#4E6834. Novaluron on *Brassica*, Head and Stem, Subgroup 5A. Review of Amendment Dated 15-Dec-2005 Submitted in Response to HED's Memo of 03-NOV-2005. Submission of Additional Plant and Livestock Radiovalidation Data.

From: S. Levy
Date: 08/23/06

DP#s: 340137 & 342004
Subject: Novaluron. Petition for the Establishment of Permanent Tolerances for New Uses on Sugarcane and Tomato (PP#7E7199); and Request for Amended Use Pattern on Head and Stem *Brassica* Vegetables. Summary of Analytical Chemistry and Residue Data.

From: G. Kramer
Date: 02/07/08

DP#: D357060
Subject: Novaluron. Petition for the Establishment of Permanent Tolerances for Residues of Novaluron in/on Bushberry Subgroup 13-07B; *Brassica*, Leafy Greens, Subgroup 5B; Turnip, Greens; and Fruit, Stone, Group 12. Summary of Analytical Chemistry and Residue Data.

From: J. L. Van Alstine
To: D. Rosenblatt /L. Nollen
Date: 09/09/09

DP#: D364237
Subject: Novaluron. Petition for the Establishment of Permanent Tolerances for Residues of Novaluron in/on Vegetable, Fruiting, Group 8; Vegetable, Cucurbit, Group 9; Berry, Low-growing, Subgroup 13-07G; Miscellaneous Fruiting Vegetables; Bean, Snap; Bean, Dry, Seed; and Swiss Chard. Summary of Analytical

Chemistry and Residue Data.

From: J. L. Van Alstine
To: B. Madden/L. Nollen
Date: 12/04/09

DP#: D374420
Subject: Novaluron. Petition for the Establishment of Permanent Tolerances for Residues of Novaluron in/on Grain Sorghum. Summary of Analytical Chemistry and Residue Data.
From: J. L. Van Alstine
To: John Hebert (RM 07)/ Jennifer Gaines
Date: 02/23/2010

Appendices:
Appendix I: International Residue Limit Status sheet
Appendix II - Tolerance-Assessment Calculations
Appendix III - Tolerance-Assessment Calculations

cc: Julie L. Van Alstine (RAB1)
RDI: G. Kramer (06-DEC-10), RAB1 Chemists (08-DEC-10)
J.L.Van Alstine:S10951:PY-S:(703)603-8866:7509P:RAB1

Template Version September 2005

Appendix I: International Residue Limit Status Sheet.

Novaluron (124002; 09-NOV-2010)

Summary of US and International Tolerances and Maximum Residue Limits.				
Residue Definition:				
US		Canada	Mexico[2]	Codex[3]
40 CFR §180.598: Plant and Livestock: *N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide		N-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy) ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide		Novaluron (fat soluble)
Commodity[1]	*Tolerance (ppm) /Maximum Residue Limit (mg/kg)*			
	US	Canada	Mexico[2]	Codex[3]
Corn, Sweet, Stover	50			
Corn, Sweet, Forage	16			
Corn, Sweet, Kernel Plus Cob With Husks Removed	0.05			
All food/feed items other than those already covered by a higher tolerance as a result of use on growing crops	0.01	2.0 apples, crabapples, loquats, mayhaws, oriental pears, pears, quinces; 0.05 arracacha, arrowroot, cassava roots, chayote roots, Chinese artichokes, chufa, edible canna, ginger roots, jerusalem artichokes; lerens, potatoes, sweet potato roots, tanier corms, true yam tubers, turmeric roots, yam bean roots		40 Apple pomace, Dry; 0.5 Cotton seed; 3 Pome fruits; 0.01 (*) Potato, Soya bean (immature seeds); 0.02 (*) Tomato
Completed: M. Negussie; 11/15/2010				

[1] Includes only commodities of interest for this action. Tolerance values should be the HED recommendations and not those proposed by the applicant.

[2] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

[3] * = absent at the limit of quantitation.

Appendix II. Tolerance-Assessment Calculations.

Sweet Corn Stover, Forage, and K+CWHR

The dataset used to establish a tolerance for novaluron in/on sweet corn consisted of field trial data for stover, forage, and K+CWHR. The stover, forage, and K+CWHR field trial data represented total application rates of 0.389-0.424 lb ai/A (5 applications of 0.077-0.088 lb ai/A/application), with 5-9 day RTIs and a 1-day PHI. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* (SOP), the field trial application rates and PHIs are within 25% of the maximum label application rate and minimum label PHI, respectively. The residue values that were entered into the tolerance spreadsheet are provided in Tables I.1, and I.2.

The sweet corn stover and forage datasets were entered into the tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP. Since all residues for sweet corn K+CWHR were less than the LLMV (0.05 ppm), the dataset was not entered into the calculator, and the recommended tolerance is 0.05 ppm. All field trial sample results for sweet corn stover and forage were above the LOQs of 0.049 ppm and 0.052 ppm, respectively. Visual inspection of the lognormal probability plots (Figures I.1 and I.3) and the Shapiro-Francia test statistic (Figures I.2 and I.4) for sweet corn stover and forage indicated that the lognormality assumption should be rejected for sweet corn stover and forage.

For sweet corn stover and forage, the mean + 3 SDs round to 50 ppm and 16 ppm, respectively (Figures I.2 and I.4). Based on the tolerance spreadsheet output and the submitted K+CWHR data, 50 ppm, 16 ppm, and 0.05 ppm are the recommended tolerance levels for novaluron in/on sweet corn stover, forage, and K+CWHR, respectively.

Sweet Corn Stover

Table I.1. Residue Data Used to Calculate Tolerance for Novaluron in/on Corn, Sweet, Stover.	
Regulator:	EPA
Chemical:	Novaluron
Crop:	Sweet Corn Stover
PHI:	1 Day
App. Rate:	0.389-0.424 lb ai/A
Submitter:	IR-4
MRID Citation:	48073501
	Residues of Novaluron (ppm)[1]
	0.46
	0.43
	7.64
	15.04
	13.87
	17.48
	44.98
	52.06
	14.7
	16.84
	10.35
	4.3

Table I.1. Residue Data Used to Calculate Tolerance for Novaluron in/on Corn, Sweet, Stover.	
	12.73
	14.48
	9.5
	9.13
	3.12
	2.46
	21.01
	19.25
	13.72
	13.22
	13.54
	17.91
	1.49
	1.3
	6.43
	6.29

[1] Values which are bolded are the average of multiple injections.

Figure I.1. Lognormal Probability Plot of Novaluron Field Trial Data for Corn, Sweet, Stover.

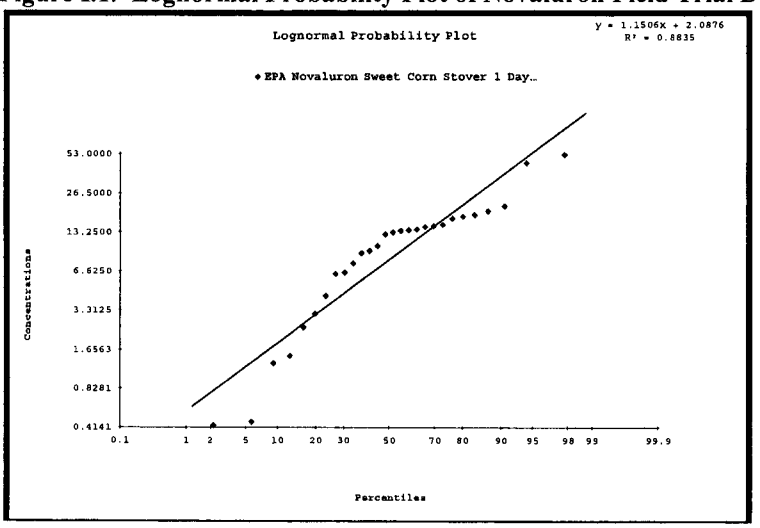


Figure I.2. Tolerance Spreadsheet Summary of Novaluron Field Trial Data for Corn, Sweet, Stover.

	Regulator: EPA		
	Chemical: Novaluron		
	Crop: Sweet Corn Stover		
	PHI: 1 Day		
	App. Rate: 0.389-0.424 lb ai/A		
	Submitter: IR-4		
	n:	28	
	min:	0.43	
	max:	52.06	
	median:	12.98	
	average:	12.99	
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	35 (40)	45 (50)	50 (--)
95/99 Rule	60 (120)	130 (330)	320 (--)
EU Method II Distribution-Free		35	
Mean+3SD		50	
UCLMedian95th		70	
Approximate Shapiro-Francia Normality Test		0.8835 p-value <= 0.01: Reject lognormality assumption	

Sweet Corn Forage

Table I.2. Residue Data Used to Calculate Tolerance for Novaluron in/on Corn, Sweet, Forage.	
Regulator:	EPA
Chemical:	Novaluron
Crop:	Sweet Corn Forage
PHI:	1 Day
App. Rate:	0.389-0.424 lb ai/A
Submitter:	IR-4
MRID Citation:	48073501
	Residues of Novaluron (ppm)[1]
	0.35
	0.44
	4.87
	3.64
	3.25
	3.82
	8.1
	14.13
	3.23
	5.29
	5.81
	3.08
	3.71
	7.83
	6.11
	5.09
	2.53
	3.25
	13.4
	9.64

Table I.2. Residue Data Used to Calculate Tolerance for Novaluron in/on Corn, Sweet, Forage.	
	11.31
	7.4
	6.46
	4.66
	1.33
	1.31
	2.6
	2.61

[1] Values which are bolded are the average of multiple injections.

Figure I.3. Lognormal Probability Plot of Novaluron Field Trial Data for Corn, Sweet, Forage.

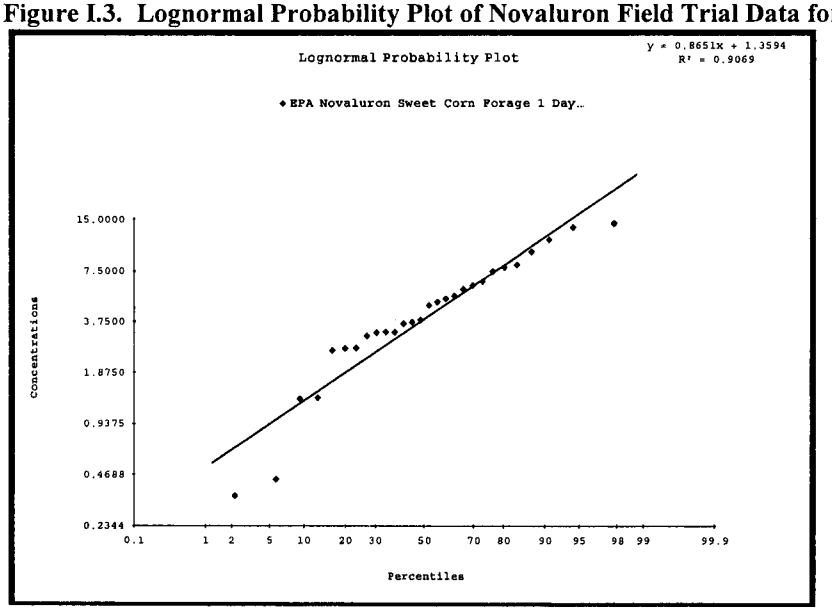


Figure I.4. Tolerance Spreadsheet Summary of Novaluron Field Trial Data for Corn, Sweet, Forage.

	Regulator:	EPA	
	Chemical:	Novaluron	
	Crop:	Sweet Corn Forage	
	PHI:	1 Day	
	App. Rate:	0.389-0.424 lb ai/A	
	Submitter:	IR-4	
	n:	28	
	min:	0.35	
	max:	14.13	
	median:	4.24	
	average:	5.19	
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	12 (14)	14 (17)	17 (--)
95/99 Rule	17 (30)	**35** (60)	60 (--)
EU Method II Distribution-Free		15	
Mean+3SD		**16**	
UCLMedian95th		**25**	
Approximate Shapiro-Francia Normality Test		0.9069	
	0.05 >= p-value > 0.01 : Reject lognormality assumption		

Appendix III. Rimon® Supra 10EC Application Rate Calculations.

These calculations were performed in order to calculate the application rate of novaluron indoors as spot, crack and crevice, surface spray, and general surface applications. The information used was provided in the simulated food-handling establishment residue study report (MRID 48034903) where a space spray treatment of Diamond® 0.83EC, containing 0.83 lb ai/gal novaluron, was applied in the form of a fine mist (i.e., fog) at an application rate of 38.75 mg ai/m^2 (target rate of 25 mg ai/m^2). This type of application represents a worst-case scenario. According to the study report, this application rate is 3X the label rate. Since only the dilution information (i.e., add 2.3 to 3.1 ounces product per gallon of water) was provided in the label, HED performed the following calculations, based on the information provided in the food-handling establishment study report, to calculate the application rate.

The following information was taken directly from the study report:

- Target delivery volume = $\frac{2 \text{ fl oz}}{1000 \text{ ft}^3}$;
- Area of room[1] = 24.3 m^2; and
- Volume of room[1] = 2027.6 ft^3.

Therefore, the total volume of spray applied was calculated as:

$$\text{Total volume of spray applied} = \frac{2 \text{ fl oz}}{1000 \text{ ft}^3} \times 2027.6 \text{ ft}^3 = 4.06 \text{ fl oz}$$

Using the total volume of spray applied within the room and the area of the room, the spray application rate was calculated as:

$$\text{Spray Application Rate} = \frac{4.06\ fl\ oz}{24.3\ m^2} x \frac{0.093\ m^2}{1\ ft^2} x \frac{1\ gal}{128\ fl\ oz} = \frac{0.0001\ gal}{ft^2} = \frac{0.1\ gal}{1000\ ft^2}.$$

Using information provided in the label and the application information provided in the study report, the ai application rate was calculated as:

$$\text{ai Application Rate} = \frac{3.1\ oz}{gal} x \frac{1\ gal}{128\ fl\ oz} x \frac{0.83\ lb\ ai}{1\ gal} x \frac{4.06\ fl\ oz}{24.3\ m^2} x \frac{1\ gal}{128\ fl\ oz} x \frac{453592.37\ mg}{1\ lb} = \frac{11.9\ mg\ ai}{m^2}.$$

The calculated ai application rate corresponds to the previously submitted study protocol statement that 25 mg ai/m^2 is 2X the label rate (Memo, J. Langsdale, 18-NOV-2008; D356505) and the study report statement that the application rate of 38.75 mg ai/m^2 is 3X the label rate. Where:

$$\frac{11.9\ mg\ ai}{m^2} x\ 2 = \frac{23.8\ mg\ ai}{m^2} \cong \frac{25\ mg\ ai}{m^2}; \text{ and}$$

$$\frac{11.9\ mg\ ai}{m^2} x\ 3 = \frac{35.7\ mg\ ai}{m^2} \cong \frac{38.75\ mg\ ai}{m^2}.$$

[1] The dimensions of the room where the trial was conducted were 11.5 ft x 22.75 ft x 7.75 ft (width x length x height).

For use in further calculations, the units for the ai application rate were converted to µg ai/cm^2:

$$\text{ai Application Rate} = \frac{11.9\ mg\ ai}{m^2} x\ \frac{1{,}000\ \mu g}{mg}\ x\ \frac{1m^2}{10{,}000\ cm^2} = \frac{1.19\ \mu g}{cm^2}.$$

Conclusions

HED requests that the label specify an application rate of 0.1 gallons per 1000 ft^2.

References

MRID 48034903 Hummel, R. (2009) Residue in Food Commodities Following Application of a Liquid Formulation of Novaluron as a Space Spray Treatment in a Simulated Food Handling Establishment. Project ID: 14521A008. Unpublished study prepared by Landis International, Inc. for Makhteshim-Agan of North America Inc. 156 p.

DP#: 356505
Subject: Review of Protocol for use of Novaluron (Rimon® 0.83EC Insecticide; EPA Reg. No. 66222-35) in Food/Feed Areas of Food-Handling Establishments.
From: J. M. Langsdale
To: K. Davis/V. Eagle
Date: 11/18/2008
MRID#s: 47528200; 47528201

Novaluron/NVU/Makhteshim Agan of North America, Inc./MKC
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial/ Residue Decline – Sweet Corn

Primary Evaluator	Melissa Watchorn, Evaluation Officer Minor Use Assessment Section, Health Evaluation Directorate, PMRA	Date: Jan 5/11
Peer Reviewer	Julie L. Van Alstine, MPH, Environmental Health Scientist Risk Assessment Branch 1 (RAB1) Health Effects Division (HED; 7509P), US EPA	Date: 05-JAN-2011
Approved by	Jennifer Selwyn, Section Head Minor Use Assessment Section, Health Evaluation Directorate, PMRA	Date: Jan 5/11
Approved by	George F. Kramer, Ph.D., Senior Chemist RAB1/HED (7509P), US EPA	Date: 1-5-11

STUDY REPORTS:

PMRA No. 1903896. MRID No. 48073501. Leonard, R.C. (2010) "Novaluron: Magnitude of the Residue on Corn (Sweet)." IR-4 PR No. 09838, Analytical Laboratory Identification No. 09838.09-JRF01. Unpublished study prepared by IR-4 Project, Rutgers, The State University of New Jersey. Princeton, NJ, USA. 676 pages.

EXECUTIVE SUMMARY:

Residue data were submitted by the Interregional Research Project Number 4 (IR-4) in support of the registration request for the use of novaluron on sweet corn in both the US and Canada. Review of these data is being conducted jointly with the US EPA and the PMRA in Canada. In the submitted study, fourteen residue trials were conducted in the US and Canada in the 2007 growing season in Zone 1 (1 in NY), Zone 2 (1 in NJ; 1 in MD), Zone 3 (1 in FL), Zone 5 (2 in ND; 2 in ON), Zone 5A (1 in WI; 1 in MI), Zone 7A (1 in AB), Zone 10 (1 in CA), Zone 11 (1 in WA), and Zone 12 (1 in OR).

Novaluron was applied to sweet corn using an emulsifiable-concentrate (EC) formulation (RimOn® 0.83 EC), as 5 directed or broadcast foliar applications, at rates of 86.3 – 98.6 g a.i./ha (0.077 – 0.088 lb a.i./A), at re-treatment intervals (RTIs) of 5 – 8 days, for total rates of 436 – 475 g a.i./ha (0.389 – 0.424 lb a.i./A). There were no adjuvants included in any of the spray mixtures. Commercially mature sweet corn kernel plus cobs with husks removed (K+CWHR), forage, and stover were harvested at a 1-day preharvest interval (PHI), and additional samples

were harvested at PHIs of 0, 2, 7, and 9 days at one trial site (MI17) to examine residue decline behaviour.

Residues of novaluron in treated sweet corn matrices were determined using a gas chromatography/electron-capture detection (GC/ECD) method based on the method entitled "Magnitude of the Residue of Novaluron in Pome Fruit Raw Agricultural and Processed Commodities" (PMRA # 1903895; MRID 45638420). A copy of this method was submitted with the field trials. The method used to analyze sweet corn has not been reviewed by the EPA or PMRA; however, the original method (Method MAK 453/972510; MRID 45638304; PMRA # 883970) has been reviewed and deemed acceptable by both Agencies. The method was validated prior to analysis of analytical sample sets. Additionally, control samples were spiked concurrently with analysis of treated sample sets to ensure the validity of the method. With the exception of one recovery (62 % in stover sample spiked concurrently with 60 ppm novaluron), all method validation and concurrent recoveries fell within the acceptable 70 – 120 % range, indicating the method is adequate for the determination of residues of novaluron in/on sweet corn K+CWHR, forage, and stover in this study. The lowest level of method validation (LLMV) is 0.05 ppm for corn K+CWHR, forage, and stover. The limit of quantitation (LOQ) was calculated to be 0.040 ppm, 0.052 ppm, and 0.049 ppm for K+CWHR, forage, and stover, respectively. The limit of detection (LOD) for the method was calculated to be 0.013 ppm, 0.017 ppm, and 0.016 ppm for K+CWHR, forage, and stover, respectively.

Treated K+CWHR, forage, and stover were stored frozen (< -20 °C) from harvest to extraction for a maximum of 785 days, 795 days, and 791 days (~ 26 months), respectively. A storage stability study was conducted concurrently with the analytical portion of the residue field trial study. Untreated control K+CWHR, forage, and stover samples from the Salisbury, MD trial (MD17) were spiked with 0.5 ppm novaluron, and stored frozen for 763 days, 775 days, and 777 days, respectively. With the exception of two recoveries (125 % and 138 % in stover), all recoveries were within the acceptable 70 – 120 % range; therefore, there are no concerns regarding the stability of residues of novaluron in/on K+CWHR, stover, and forage matrices in this study.

Residues of novaluron in treated K+CWHR samples were all < 0.05 ppm when treated with 5 foliar applications of novaluron at total rates of 436 – 475 g a.i./ha (0.389 – 0.424 lb a.i./A), when samples were harvested at a 1-day PHI. Residues of novaluron in treated sweet corn forage and stover ranged from 0.35 – 14.13 ppm, and from 0.43 – 52.06 ppm, respectively, when treated at the same rates and harvested at a 1-day PHI. Residues of novaluron appeared to increase with increasing PHI in both sweet corn forage and stover when harvested at PHIs of 0, 1, 2, 7, and 9 days. Residues of novaluron in K+CWHR were all < 0.05 ppm when harvested at PHIs of 0, 1, 2, 7, and 9 days.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the field trial residue data are classified as scientifically acceptable.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document [DP Barcode 378631] and in Canada's Evaluation Report.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. The study meets current GLP requirements of 40 CFR Part 160, except as noted below. These deviations do not affect the results presented in the study.

1. Supporting field data such as soil characteristics, weather, irrigation, cultural practices, site history records, and maintenance chemical applications were not collected in adherence to 40 CFR Part 160 guidelines.

2. At trials NY07, NJ27, MD16, MI17, ND06, ND07, WI 25, ON24, and ON21, some of the equipment maintenance records were not maintained in a fully GLP compliant manner. The check box in the Field Data Book was marked by the FRDs in this study. This box was intended to be, and is being interpreted to mean, that not all of the equipment at the test site has fully GLP compliant maintenance records and it is not being used as an all inclusive statement.

3. At trials, NY07, NJ27, MD16, MI17, ND06, ND07, WI25, CA75, OR13, ON24, and AB02, the pH determination of the carrier water was not determined according to GLP.

4. At trials, NY07, NJ27, MD16, FL23, MI17, ND06, ND07, WI25, CA75, OR13, and ON21, the RAC sample weights were not determined according to GLP requirements.

5. The freezer at the Michigan field site is common use equipment and no maintenance or repair records are kept. During the field season, the temperature monitoring system is verified and records are maintained.

6. At the NY07 site the REVCO temperature recorder was not calibrated prior to its use.

7. At the OR13 the Field Research Director recorded the application pass times on the gloves she was wearing and transcribed that data into the Field Residue Notebook. The Field Residue Notebook also contains copies of the data recorded on the gloves.

A. BACKGROUND INFORMATION

Novaluron is a chitin synthesis inhibitor, affecting moulting. It is absorbed mainly by ingestion, but shows some contact activity and is effective against larvae, but also has a toxic effect on eggs of some species, and in some cases, reduces fecundity.

TABLE A.1. Test Compound Nomenclature.

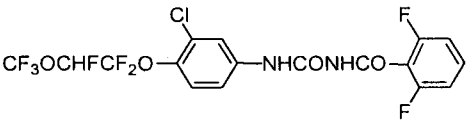
Compound	Chemical Structure
	
Common name	Novaluron
Company experimental name	Not applicable.
IUPAC name	(±)-1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea
CAS name	(±)-*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide
CAS #	116714-46-6
End-use product/(EP)	RimOn® 0.83 EC Insecticide

TABLE A.2. Physicochemical Properties of Novaluron

Parameter	Value		Reference
Melting point/range	176.5 – 178 °C		e-Pesticide Manual, Version 3.1 DP#s 322978 & 315780, 11/3/05, S. Levy
pH	6.5		
Specific gravity at 22 °C	1.56 g/cm^3		
Water solubility at 25 °C	3 µg/L		
Solvent solubility	Solvent	Solubility (g/L)	PRD2006-05 DP#s 322978 & 315780, 11/3/05, S. Levy
	n-heptane	8.39 (mg/L)	
	xylene	1.88	
	1,2-dichloroethane	2.85	
	methanol	14.5	
	acetone	198.5	
	ethyl acetate	113.0	
	n-octanol	0.98	
Vapour pressure at 25 °C	1.6 X 10^{-5} Pa		
Dissociation constant (pK_a)	Not investigated due to the low water solubility of the test material.		
Octanol/water partition coefficient Log(K_{OW}) at 25 °C	$\log K_{ow} = 4.3$		
UV/visible absorption spectrum	$\lambda_{max} = 253$ nm		

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State or Province/Year)	Soil characteristics				Meteorological Data	
	Type	%OM*	pH*	CEC* meq/g	Rainfall	Temperature
Trial ID # 07-NY07 (Freeville, NY/2007)	Loam	6.38	7.04	Not determined	Normal	Normal
Trial ID # 07-NJ27 (Bridgeton, NJ/2007)	Sandy Loam	1.4	6.2	4.8	June precipitation was above average. July and August precipitation were below average. Irrigation was used to supplement rainfall.	June and August temperatures were above average. July temperatures were normal.
Trial ID # 07-MD16 (Salisbury, MD/2007)	Sand	0.8	6.2 (Field 32) 6.1 (Field 33)	2.8 (Field 32) 3.0 (Field 33)	Rainfall was well below average. Irrigation was used to supplement rainfall.	Normal
Trial ID # 07-FL23 (Citra, FL/2007)	Loamy Sand	1.3	6.1	6.6	Normal. Irrigation was used to supplement rainfall.	Normal
Trial ID # 07-WI25 (Arlington, WI/2007)	Silt Loam	3.6	7.0	20	Normal	Normal
Trial ID # 07-MI17 (Holt, MI/2007)	Sandy Loam	1.3	6.2	4.5	It was very dry during July and August. Irrigation was used to supplement rainfall.	Normal
Trial ID # 07-ND06 (Fargo, ND/2007)	Silty Clay	5.5	8.0	27.8	Excess rainfall in May and June resulted in some standing water and saturated soil that stunted plant growth. July was well below normal for precipitation.	May, June and July had above normal temperatures.
Trial ID # 07-ND07 (Fargo, ND/2007)	Silty Clay	5.5	8.0	27.8		
Trial ID # 07-OR13 (Aurora, OR/2007)	Loam	5.3	6.4	Not determined	Normal. Irrigation was used to supplement rainfall.	Normal
Trial ID # 07-WA22 (Prosser, WA/2007)	Silt Loam	1.10	7.8	12.5	Normal. Irrigation was used to supplement rainfall.	Normal
Trial ID # 07-CA75 (Irvine, CA/2007)	Sandy Loam	1.0	7.7	28.9	Normal. Irrigation was used to supplement rainfall.	Normal

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State or Province/Year)	Soil characteristics				Meteorological Data	
	Type	%OM*	pH*	CEC* meq/g	Rainfall	Temperature
Trial ID # 07-ON21 (Delhi, ON/2007)	Loamy Sand	1.3-1.8	6.1-6.6	4	Below normal rainfall from April to July was supplemented with irrigation. Average rainfall was observed in August.	Normal
Trial ID # 07-ON24 (Branchton, ON/2007)	Loam	0.99	6.2	5.4 cmol/kg	Normal	Normal
Trial ID # 07-AB02 (Tabor, AB/2007)	Sandy Loam	2.9	7.5	15	Normal average rainfall was experienced in May. All other months had below normal average rainfall.	June and July temperatures were above normal. Temperatures for all other months were normal.

*These parameters are optional except in cases where their value affects the use pattern for the chemical. OM = organic matter; CEC = cation-exchange capacity.

TABLE B.1.2. Study Use Pattern.

Trial Identification (City, State or Province/Year)	EP[1]	Application					Tank Mix/ Adjuvants
		Method/Timing	Volume L/ha [Gallons/A]	Rate g a.i./ha [lb a.i./A]	RTI[2] (days)	Total Rate g a.i./ha [lb a.i./A]	
Trial ID # 07-NY07 (Freeville, NY/2007)	RimOn® 0.83 EC	Directed foliar/ 12-14 leaves; 160-180 cm	467 [49.9]	88.5 [0.079]	--	446 [0.398]	None
		Directed foliar/ 14-15 leaves; 170 cm	470 [50.3]	89.7 [0.08]	7		
		Directed foliar/ 15 leaves; 170 cm	468 [50.0]	88.5 [0.079]	8		
		Directed foliar/ 15-17 leaves; 170-190 cm	468 [50.1]	89.7 [0.08]	8		
		Directed foliar/ 16 leaves; 170-180 cm	470 [50.3]	89.7 [0.08]	6		
Trial ID # 07-NJ27 (Bridgeton, NJ/2007)	RimOn® 0.83 EC	Directed foliar/ Fruiting; 183-198 cm	258 [27.6]	88.5 [0.079]	--	475 [0.424]	None
		Directed foliar/ Fruiting; 183-198 cm	356 [38.1]	98.6 [0.088]	6		
		Directed foliar/ Fruiting; 229-244 cm	368 [39.4]	96.4 [0.086]	6		
		Directed foliar/ Fruiting; 244 cm	372 [39.8]	94.2 [0.084]	9		
		Directed foliar/ Fruiting; 244 cm	369 [39.5]	97.5 [0.087]	6		
Trial ID # 07-MD16 (Salisbury, MD/2007)	RimOn® 0.83 EC	Directed foliar/ Full tassel/84 cm	254 [27.2]	89.7 [0.08]	--	444 [0.396]	None
		Directed foliar/ Full tassel; 102 cm	250 [26.7]	88.5 [0.079]	7		
		Directed foliar/ Wilted Silk; 107 cm	252 [26.9]	88.5 [0.079]	7		
		Directed foliar/ Brown Silk; 107-122 cm	250 [26.7]	88.5 [0.079]	6		
		Directed foliar/ Mature; 107-122 cm	252 [27.0]	88.5 [0.079]	6		

TABLE B.1.2. Study Use Pattern.

Trial Identification (City, State or Province/Year)	EP[1]	Application					Tank Mix/ Adjuvants
		Method/Timing	Volume L/ha [Gallons/A]	Rate g a.i./ha [lb a.i./A]	RTI[2] (days)	Total Rate g a.i./ha [lb a.i./A]	
Trial ID # 07-FL23 (Citra, FL/2007)	RimOn® 0.83 EC	Directed foliar/ Corn ear forming; 102-112 cm	380 [40.6]	91.9 [0.082]	--	460 [0.410]	None
		Directed foliar/ Fruiting; 97-137 cm	381 [40.7]	91.9 [0.082]	7		
		Directed foliar/ Ears half mature; 102-137 cm	382 [40.9]	91.9 [0.082]	6		
		Directed foliar/ Mature ears; 102-137 cm	379 [40.5]	90.8 [0.081]	7		
		Directed Foliar/ Fruiting; 107-132 cm	384 [41.1]	93.0 [0.083]	7		
Trial ID # 07-WI25 (Arlington, WI/2007)	RimOn® 0.83 EC	Broadcast foliar/ Early tassel; 152 cm	248 [26.5]	93.0 [0.083]	--	462 [0.412]	None
		Broadcast foliar/ Tassel; 152 cm	293 [31.3]	91.9 [0.082]	7		
		Broadcast foliar/ Tasseling; 183 cm	277 [29.6]	91.9 [0.082]	7		
		Broadcast foliar/ Tasseling; 183 cm	299 [32.0]	93.0 [0.083]	7		
		Broadcast foliar/ Tasseling; 183 cm	312 [33.4]	91.9 [0.082]	7		
Trial ID # 07-MI17 (Holt, MI/2007)	RimOn® 0.83 EC	Broadcast foliar/ Tassel; 137-152 cm	275 [29.4]	88.5 [0.079]	--	436 [0.389]	None
		Broadcast foliar/ Tassel, silk; 137-152 cm	277 [29.6]	88.5 [0.079]	6		
		Broadcast foliar/ Silking; 137-152 cm	270 [28.9]	86.3 [0.077]	7		
		Broadcast foliar/ Silking; 152 cm	270 [28.9]	86.3 [0.077]	7		
		Broadcast foliar/ Fruiting; 152 cm	269 [28.8]	86.3 [0.077]	6		
Trial ID # 07-ND06 (Fargo, ND/2007)	RimOn® 0.83 EC	Broadcast foliar/ Tassel emergence; 107 cm	167 [17.9]	89.7 [0.08]	--	449 [0.400]	None
		Broadcast foliar/ Growth stage R1; 152 cm	167 [17.9]	89.7 [0.08]	6		
		Broadcast foliar/ Growth stage R2; 152 cm	167 [17.8]	89.7 [0.08]	8		
		Broadcast foliar/ Blister stage; 152 cm	167 [17.8]	89.7 [0.08]	7		
		Broadcast foliar/ Milk stage; 145 cm	168 [18.0]	89.7 [0.08]	6		
Trial ID # 07-ND07 (Fargo, ND/2007)	RimOn® 0.83 EC	Broadcast foliar/ Tassel emergence; 104 cm	168 [18.0]	90.8 [0.081]	--	447 [0.399]	None
		Broadcast foliar/ Silk stage; 157 cm	167 [17.9]	89.7 [0.08]	6		
		Broadcast foliar/ Blister stage; 157 cm	166 [17.7]	88.5 [0.079]	8		
		Broadcast foliar/ Late blister; 157 cm	166 [17.7]	88.5 [0.079]	7		
		Broadcast foliar/ Milk; 147 cm	167 [17.9]	89.7 [0.08]	6		

TABLE B.1.2. Study Use Pattern.

Trial Identification (City, State or Province/Year)	EP[1]	Application					Tank Mix/ Adjuvants
		Method/Timing	Volume L/ha [Gallons/A]	Rate g a.i./ha [lb a.i./A]	RTI[2] (days)	Total Rate g a.i./ha [lb a.i./A]	
Trial ID # 07-OR13 (Aurora, OR/2007)	RimOn® 0.83 EC	Directed foliar/ Tassels; 152-183 cm	414 [44.3]	93.0 [0.083]	--	449 [0.401]	None
		Directed foliar/ Ear formation; 152-183 cm	452 [48.3]	88.5 [0.079]	6		
		Directed foliar/ Ears maturing; 183 cm	454 [48.5]	88.5 [0.079]	5		
		Directed foliar/ Ears maturing; 183 cm	458 [49.0]	89.7 [0.08]	5		
		Directed foliar/ Commercially mature; 152 cm	459 [49.1]	89.7 [0.08]	5		
Trial ID # 07-WA22 (Prosser, WA/2007)	RimOn® 0.83 EC	Broadcast foliar/ Silking; 183-213 cm	249 [26.6]	90.8 [0.081]	--	451 [0.402]	None
		Broadcast foliar/ Vegetative; 183-213 cm	248 [26.5]	88.5 [0.079]	7		
		Broadcast foliar/ Vegetative; 183-213 cm	272 [29.1]	89.7 [0.08]	6		
		Broadcast foliar/ Vegetative; 183-213 cm	270 [28.9]	91.9 [0.082]	7		
		Broadcast foliar/ Vegetative; 183-213 cm	264 [28.2]	89.7 [0.08]	7		
Trial ID # 07-CA75 (Irvine, CA/2007)	RimOn® 0.83 EC	Directed foliar/ Vegetative; 107 cm	284 [30.4]	90.8 [0.081]	--	451 [0.402]	None
		Directed foliar/ Silk; 152 cm	326 [34.8]	89.7 [0.08]	7		
		Directed foliar/ Silk; 183 cm	372 [39.8]	89.7 [0.08]	7		
		Directed foliar/ Silk; 183 cm	379 [40.5]	90.8 [0.081]	7		
		Directed foliar/ Mature; 183 cm	374 [40.0]	89.7 [0.08]	7		
Trial ID # 07-ON21 (Delhi, ON/2007)	RimOn® 0.83 EC	Directed foliar/ 8-10 true leaves; 120 cm	548 [58.5]	89.7 [0.08]	--	452 [0.404]	None
		Broadcast foliar/ Tassel development; 155 cm	550 [58.8]	90.4 [0.081]	7		
		Broadcast foliar/ Early ear formation; 180 cm	558 [59.6]	91.7 [0.082]	6		
		Broadcast foliar/ Ear formation; 190 cm	550 [58.8]	90.4 [0.081]	7		
		Broadcast foliar/ Fruiting; 200 cm	549 [58.7]	90.2 [0.080]	7		
Trial ID # 07-ON24 (Branchton, ON/2007)	RimOn® 0.83 EC	Broadcast foliar/ 6-8 leaves; 100 cm	302 [32.3]	89.9 [0.080]	--	448 [0.400]	None
		Broadcast foliar/ 6-9 leaves; 125-130 cm	303 [32.4]	90.4 [0.081]	6		
		Broadcast foliar/ 15-20 cm cobs; 160-170 cm	300 [32.1]	89.4 [0.080]	7		
		Broadcast foliar/ 20-25 cm cobs; 170 cm	300 [32.1]	89.3 [0.080]	6		
		Broadcast foliar/ 20 cm cobs; 145 cm	297 [31.8]	88.5 [0.079]	8		

TABLE B.1.2. Study Use Pattern.

Trial Identification (City, State or Province/Year)	EP[1]	Application					Tank Mix/ Adjuvants
		Method/Timing	Volume L/ha [Gallons/A]	Rate g a.i./ha [lb a.i./A]	RTI[2] (days)	Total Rate g a.i./ha [lb a.i./A]	
Trial ID # 07-AB02 (Tabor, AB/2007)	RimOn® 0.83 EC	Broadcast foliar/ BBCH 37-51; 120-130 cm	213 [22.8]	96.1 [0.086]	--	454 [0.406]	None
		Broadcast foliar/ BBCH 59-63; 180-200 cm	196 [21.0]	88.5 [0.079]	7		
		Broadcast foliar/ BBCH 65-67; 210-220 cm	201 [21.5]	90.6 [0.081]	7		
		Broadcast foliar/ BBCH 71-73; 210-220 cm	199 [21.2]	89.8 [0.080]	6		
		Broadcast foliar/ BBCH 75-79; 210-220 cm	198 [21.2]	89.2 [0.080]	8		

[1]EP = End-use Product.
[2] RTI = Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA[1] Growing Zones	Sweet Corn		
	Submitted	Requested	
		Canada	U.S.[2]
1	1		2
2	2		1
3	1		1
5	4	4	5
5A	2		
5B		2	
7A	1	1	
10	1		1
11	1		1
12	1	1	1
Total	14	8	12

[1] NAFTA = North American Free Trade Agreement.
[2] As per OPPTS 860.1500, Tables 1 and 5 for sweet corn.

B.2. Sample Handling and Preparation

Commercially mature sweet corn were harvested by hand with a knife, a sickle, pruning shears, or loppers, first from the untreated, and then from treated plots, to avoid contamination. A minimum of twelve plants were collected randomly from each plot, avoiding plot ends. Cobs were removed from husks, placed into sample bags, and placed in frozen storage within 3 hours of harvest. The stalks were cut into three equal lengths, with samples of tops, middles and

bottoms placed in sample bags for forage samples. These samples were also placed in frozen storage within 3 hours of harvest. Stover samples were prepared the same way as the forage samples, however, they were dried in the field, in greenhouses, or in a dryer for 2 to 16 days (moisture content ~ 15 – 28 %) prior to being placed in frozen storage. Samples from the Holt, MI (MI17) trial site were hand delivered to the analytical facility, while samples from the remaining sites were shipped frozen by ACDS freezer truck. Upon arrival at the analytical facility, samples were placed in frozen storage (<-20 °C). Samples were processed by chopping with equal amounts of dry ice in a Hobart chopper, and were returned to frozen storage, where they remained, until extraction and analysis.

B.3. Analytical Methodology

Residues of novaluron in treated sweet corn matrices were determined using a GC/ECD method based on the method entitled "Magnitude of the Residue of Novaluron in Pome Fruit Raw Agricultural and Processed Commodities" (PMRA # 1903895; MRID 45638420). A copy of this method was submitted with the field trial. The method used to analyze sweet corn has not been reviewed by the EPA or PMRA; however, the original method (Method MAK 453/972510; MRID 45638304; PMRA # 883970) has been reviewed and deemed acceptable by both Agencies.

Briefly, samples were extracted with methanol (MeOH):water (70:30; v:v) twice, and the filtrates were combined. The volume was adjusted with 100 % MeOH, aqueous (5 %) NaCl and hexane were added, and the sample was partitioned. This step was repeated, and the combined hexane extracts were evaporated to a low volume using a rotary evaporator. The mixture was centrifuged, and the hexane layer was cleaned up on a NH_2 solid-phase extraction (SPE) cartridge, eluted with diethyl ether:ethyl acetate (50:50; v:v). The solvent was evaporated under nitrogen, and then residues were determined by gas chromatography with electron capture detection (GC/ECD). The LLMV was determined to be 0.05 ppm for corn K+CWHR, forage, and stover. The LOQ was calculated to be 0.040 ppm, 0.052 ppm, and 0.049 ppm for K+CWHR, forage, and stover, respectively. The LOD for the method was calculated to be 0.013 ppm, 0.017 ppm, and 0.016 ppm for K+CWHR, forage, and stover, respectively.

The method was validated prior to sample analysis by spiking control K+CWHR, forage, and stover with 0.05 ppm, 0.5 ppm, and 5 ppm novaluron (see Table C.1). Recoveries ranged from 83 – 116 % (with standard deviations [SDs] of 1 – 12 %) in all matrices, indicated the method accurately determines residues of novaluron in K+CWHR, forage, and stover. To confirm analytical results from the field trials were reliable, control K+CWHR samples were spiked with 0.05 ppm, 0.5 ppm, and 5 ppm novaluron concurrently with the analytical sample sets. Additionally, forage samples were spiked with 0.05 ppm, 0.5 ppm, 5 ppm, and 25 ppm novaluron concurrently with the analytical sets. And, finally, control stover samples were spiked with 0.05 ppm, 0.5 ppm, 1 ppm, 5 ppm, and 60 ppm novaluron concurrently with the analytical sample sets. With the exception of one recovery (62 % in stover sample spiked with 60 ppm novaluron), all concurrent recoveries fell within the acceptable 70 – 120 % range, indicating the method is adequate for the determination of residues of novaluron in/on corn K+CWHR, forage, and stover in this study.

C. RESULTS AND DISCUSSION

Fourteen residue trials were conducted in the US and Canada in the 2007 growing season in Zone 1 (1 in NY), Zone 2 (1 in NJ; 1 in MD), Zone 3 (1 in FL), Zone 5 (2 in ND; 2 in ON), Zone 5A (1 in WI; 1 in MI), Zone 7A (1 in AB), Zone 10 (1 in CA), Zone 11 (1 in WA), and Zone 12 (1 in OR). Novaluron was applied to sweet corn using an EC formulation (RimOn® 0.83 EC), as 5 directed or broadcast foliar applications, at rates of 86.3 – 98.6 g a.i./ha (0.077 – 0.088 lb a.i./A), at RTIs of 5 – 8 days, for total rates of 436 – 475 g a.i./ha (0.389 – 0.424 lb a.i./A). There were no adjuvants included in any of the spray mixtures. Commercially mature sweet corn K+CWHR, forage, and stover were harvested at a 1-day PHI, and additional samples were harvested at PHIs of 0, 2, 7, and 9 days at one trial site (MI17) to examine residue decline behaviour. There was one treated plot, and one untreated plot at each trial site.

Residues of novaluron in treated sweet corn matrices were determined using a GC/ECD method based on the method entitled "Magnitude of the Residue of Novaluron in Pome Fruit Raw Agricultural and Processed Commodities" (PMRA # 1903895; MRID 45638420). The method used to analyze sweet corn has not been reviewed by the EPA or PMRA; however, the original method (Method MAK 453/972510; MRID 45638304; PMRA # 883970) has been reviewed and deemed acceptable by both Agencies. The LLMV was determined to be 0.05 ppm for corn K+CWHR, forage, and stover. The LOQ was calculated to be 0.040 ppm, 0.052 ppm, and 0.049 ppm for K+CWHR, forage, and stover, respectively. The LOD for the method was calculated to be 0.013 ppm, 0.017 ppm, and 0.016 ppm for K+CWHR, forage, and stover, respectively. The method was validated prior to sample analysis by spiking control K+CWHR, forage, and stover with 0.05 ppm, 0.5 ppm, and 5 ppm novaluron. All method validation recoveries were within the acceptable 70 – 120 % range. To confirm analytical results from the field trials were reliable, control K+CWHR samples were spiked with 0.05 ppm, 0.5 ppm, and 5 ppm novaluron concurrently with the analytical sample sets. Additionally, forage samples were spiked with 0.05 ppm, 0.5 ppm, 5 ppm, and 25 ppm novaluron concurrently with the analytical sets. And finally, control stover samples were spiked with 0.05 ppm, 0.5 ppm, 1 ppm, 5 ppm, and 60 ppm novaluron concurrently with the analytical sample sets. With the exception of one recovery (62 % in stover sample spiked with 60 ppm novaluron), all concurrent recoveries fell within the acceptable 70 – 120 % range, indicating the method is adequate for the determination of residues of novaluron in/on sweet corn K+CWHR, forage, and stover in this study. Sample chromatograms were provided for blanks, calibration standards, controls, spiked samples, and treated samples for all three matrices. Overall, peaks were well defined and symmetrical, and untreated controls were free from interference above the chromatographic background. In the submitted calibration curves, detector linearity was demonstrated across a seven-point range of residues (0.005 – 0.1 ppm; $R^2 \geq 0.975$) for K+CWHR, forage, and stover.

Treated K+CWHR, forage, and stover were stored frozen (< -20 °C) from harvest to extraction for a maximum of 785 days, 795 days, and 791 days (~ 26 months), respectively (Table C.2). A storage stability study was conducted concurrently with the analytical portion of the residue field trial study. Untreated control K+CWHR, forage, and stover samples from the Salisbury, MD trial (MD17) were spiked with 0.5 ppm novaluron, and stored frozen for 763 days, 775 days, and 777 days, respectively. Recoveries in spiked K+CWHR, forage, and stover samples ranged from 95 –

118 % (n = 3), from 96 - 119 % (n = 3), and from 109 – 138 % (n = 3), respectively. The study indicated that concurrent recoveries ranged from 100 – 120 %, but did not give individual recoveries. With the exception of two recoveries (125 % and 138 % in stover), all recoveries were within the acceptable 70 – 120 % range, therefore, there are no concerns regarding the stability of residues of novaluron in/on K+CWHR, stover and forage matrices in this study.

Residues of novaluron in treated K+CWHR samples were all < 0.05 ppm when treated with 5 foliar applications of novaluron at rates of 86.3 – 98.6 g a.i./ha (0.077 – 0.088 lb a.i./A), for total rates of 436 – 475 g a.i./ha (0.389 – 0.424 lb a.i./A), when samples were harvested at a 1-day PHI (Table C.3 and C.4). Residues of novaluron in treated sweet corn forage and stover ranged from 0.35 – 14.13 ppm, and from 0.43 – 52.06 ppm, respectively, when treated at the same rate and harvested at a 1-day PHI. Residues of novaluron appeared to increase with increasing PHI in both sweet corn forage and stover when harvested at PHIs of 0, 1, 2, 7, and 9 days. Residues of novaluron in K+CWHR were all < 0.05 ppm when harvested at PHIs of 0, 1, 2, 7, and 9 days.

TABLE C.1. Summary of Method Validation and Concurrent Recoveries of Novaluron from Sweet Corn.

Matrix	Recovery Type	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± std dev* (%)
Novaluron					
K+CWHR**	Method Validation	0.05	3	108, 104, 105	106 ± 2
		0.5	3	99, 99, 83	94 ± 9
		5	3	116, 105, 95	105 ± 11
	Concurrent Recovery	0.05	6	98, 94, 105, 91, 115, 122	104 ± 12
		0.5	6	99, 92, 80, 113, 119, 109	102 ± 15
		5	2	92, 97	95
Stover	Method Validation	0.05	3	83, 89, 86	86 ± 3
		0.5	3	103, 98, 116	106 ± 9
		5	3	107, 110, 103	107 ± 4
	Concurrent Recovery	0.05	8	99, 106, 85, 111, 109, 93, 118, 94	102 ± 11
		0.5	10	86, 88, 78, 83, 86, 94, 83, 107, 99, 101	91 ± 9
		1	1	78	--
		5	2	81, 80	81
		60	3	62, 71, 80	71 ± 9
Forage	Method Validation	0.05	3	106, 96, 83	95 ± 12
		0.5	3	108, 106, 107	107 ± 1
		5	3	116, 109, 110	112 ± 4
	Concurrent Recovery	0.05	10	110, 91, 117, 118, 77, 113, 109, 94, 103, 90	102 ± 14
		0.5	11	99, 116, 96, 102, 97, 96, 85, 82, 98, 108, 112	99 ± 10
		5	6	72, 76, 90, 75, 85, 88	81 ± 8
		25	3	123, 111, 122	119 ± 7

* Standard deviation is only calculated for sample sizes ≥3.
** K+CWHR = kernels plus cob with husk removed.

TABLE C.2. Summary of Storage Conditions.

Matrix (RAC)	Storage Temperature (°C)	Actual Storage Duration (days)*	Interval of Demonstrated Storage Stability (days)
K+CWHR**	<-20	785	A storage stability study was conducted concurrently with the analytical portion of the residue field trial study. Untreated control K+CWHR, forage, and stover samples from the Salisbury, MD trial (MD17) were spiked with 0.5 ppm novaluron, and stored frozen for 763 days, 775 days, and 777 days, respectively. Recoveries in spiked K+CWHR, forage, and stover samples ranged from 95 – 118 % (n = 3), from 96 - 119 % (n = 3), and from 109 – 138 % (n = 3), respectively. The study indicated that concurrent recoveries ranged from 100 – 120 %, but did not give individual recoveries. With the exception of two recoveries (125 % and 138 % in stover), all recoveries were within the acceptable 70 – 120 % range, therefore, there are no concerns regarding the stability of residues of novaluron in/on K+CWHR, stover and forage matrices in this study.
Forage		795	
Stover		791	

* From harvest to extraction. Samples were analyzed within 11 days of extraction.
**K+CWHR = kernels plus cob with husk removed.

TABLE C.3. Residue Data from Crop Field Trials with Novaluron.

Trial Identification (City, State or Province /Year)	Zone	Crop/ Variety	Commodity or Matrix	Total Rate g a.i./ha [lb a.i./A]	PHI (days)	Residues (ppm)
Trial ID # 07-NY07 (Freeville, NY/2007)	1	Bonus	K+CWHR	446 [0.398]	1	<0.05, <0.05
			Forage			0.35, 0.44
			Stover			0.46*, 0.43*
Trial ID # 07-NJ27 (Bridgeton, NJ/2007)	2	Argent	K+CWHR	475 [0.424]	1	<0.05, <0.05
			Forage			4.87*, 3.64*
			Stover			7.64, 15.04
Trial ID # 07-MD16 (Salisbury, MD/2007)	2	Quickie	K+CWHR	444 [0.396]	1	<0.05, <0.05
			Forage			3.25*, 3.82*
			Stover			13.87, 17.48
Trial ID # 07-FL23 (Citra, FL/2007)	3	281A	K+CWHR	460 [0.410]	1	<0.05, <0.05
			Forage			8.10, 14.13
			Stover			44.98, 52.06
Trial ID # 07-WI25 (Arlington, WI/2007)	5A	Jubilee Super Sweet	K+CWHR	462 [0.412]	1	<0.05, <0.05
			Forage			3.23*, 5.29*
			Stover			14.70, 16.84
Trial ID # 07-MI17 (Holt, MI/2007)	5A	Triple Sweet Hybrid	K+CWHR	436 [0.389]	0	<0.05, <0.05
			Forage			0.79, 0.11
			Stover			5.28, 3.98
			K+CWHR		1	<0.05, <0.05
			Forage			5.81, 3.08
			Stover			10.35, 4.30
			K+CWHR		2	<0.05, <0.05
			Forage			2.25, 1.35
			Stover			4.12, 7.96
			K+CWHR		7	<0.05, <0.05
			Forage			13.34*, 4.05*
			Stover			14.33, 3.40
			K+CWHR		9	<0.05, <0.05
			Forage			7.54*, 3.47*

TABLE C.3. Residue Data from Crop Field Trials with Novaluron.

Trial Identification (City, State or Province /Year)	Zone	Crop/ Variety	Commodity or Matrix	Total Rate g a.i./ha [lb a.i./A]	PHI (days)	Residues (ppm)
			Stover			14.82, 7.48
Trial ID # 07-ND06 (Fargo, ND/2007)	5	Ambrosia	K+CWHR	449 [0.400]	1	<0.05, <0.05
			Forage			3.71, 7.83
			Stover			12.73, 14.48
Trial ID # 07-ND07 (Fargo, ND/2007)	5	Applause	K+CWHR	447 [0.399]	1	<0.05, <0.05
			Forage			6.11*, 5.09*
			Stover			9.5, 9.13
Trial ID # 07-OR13 (Aurora, OR/2007)	12	Jubilee SS	K+CWHR	449 [0.401]	1	<0.05, <0.05
			Forage			2.53, 3.25
			Stover			3.12, 2.46
Trial ID # 07-WA22 (Prosser, WA/2007)	11	Super Sweet	K+CWHR	451 [0.402]	1	<0.05, <0.05
			Forage			13.40*, 9.64*
			Stover			21.01, 19.25
Trial ID # 07-CA75 (Irvine, CA/2007)	10	Legend	K+CWHR	451 [0.402]	1	<0.05, <0.05
			Forage			11.31, 7.40
			Stover			13.72, 13.22
Trial ID # 07-ON21 (Delhi, ON/2007)	5	Lancelot	K+CWHR	452 [0.404]	1	<0.05, <0.05
			Forage			6.46*, 4.66*
			Stover			13.54, 17.91
Trial ID # 07-ON24 (Branchton, ON/2007)	5	Ambrosia	K+CWHR	448 [0.400]	1	<0.05, <0.05
			Forage			1.33, 1.31
			Stover			1.49, 1.30
Trial ID # 07-AB02 (Tabor, AB/2007)	7A	Xtra Sweet 82	K+CWHR	454 [0.406]	1	<0.05, <0.05
			Forage			2.60, 2.61
			Stover			6.43, 6.29

* Average of multiple injections.

TABLE C.4. Summary of Residue Data from Crop Field Trials with Novaluron.

Commodity	Total Applic. Rate g a.i./ha [lb a.i./A]	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT*	Median (STMdR)*	Mean (STMR)*	Std. Dev.
K+CWHR	436-475 [0.389-0.424]	1	28	<0.05	<0.05	<0.05	<0.05	<0.05	0
Forage			28	0.35	14.13	11.52	4.24	5.19	3.58
Stover			28	0.43	52.06	48.52	12.98	12.99	11.77

* HAFT = Highest-Average Field Trial; STMdR = Supervised Trial Median Residues; STMR = Supervised Trial Mean Residues

D. CONCLUSION

The supervised crop field trials for novaluron on sweet corn are considered scientifically valid. Fourteen residue trials were conducted on sweet corn in Zone 1 (1 in NY), Zone 2 (1 in NJ; 1 in MD), Zone 3 (1 in FL), Zone 5 (2 in ND; 2 in ON), Zone 5A (1 in WI; 1 in MI), Zone 7A (1 in AB), Zone 10 (1 in CA), Zone 11 (1 in WA), and Zone 12 (1 in OR). Novaluron was applied to sweet corn as 5 foliar applications, at total rates of 436 – 475 g a.i./ha (0.389 – 0.424 lb a.i./A).

Residues of novaluron in treated K+CWHR samples were all < 0.05 ppm when treated with 5 foliar applications of novaluron at total rates of 436 – 475 g a.i./ha (0.389 – 0.424 lb a.i./A),

when samples were harvested at a 1-day PHI. Residues of novaluron in treated sweet corn forage and stover ranged from 0.35 – 14.13 ppm, and from 0.43 – 52.06 ppm, respectively, when treated at the same rate and harvested at a 1-day PHI. Residues of novaluron appeared to increase with increasing PHI in both sweet corn forage and stover when harvested at PHIs of 0, 1, 2, 7, and 9 days. Residues of novaluron in K+CWHR were all < 0.05 ppm when harvested at PHIs of 0, 1, 2, 7, and 9 days.

E. REFERENCES

PMRA # 883970. MRID 45638304. Todd, M.A. (1998) "Development and Validation of an Analytical Method for the Determination of Rimon in Apples, Cabbages and Potatoes". MAK453/972510. Huntingdon Life Sciences Project Identity MAK453; Makhteshin Report No. R-9345. Unpublished study prepared by Huntingdon Life Sciences, Ltd., Suffolk, England, 51 pages.

DP#s: 285474, 287627, 297094, 297228, and 298477
Subject: PP#2F06430. Novaluron. Petition for the Establishment of Permanent Tolerances for Use on Cotton, Pome Fruits, and Potato. Summary of Analytical Chemistry and Residue Data.
From: G. Kramer
To: D. Kenny
Dated: 3/22/04
MRIDs: 45638226, 45638227, 45638301-45638308, 45638311, 45638312, 45638412, 45638420, 45771801-45771803, 45785804, 45789202, 46141001, 46082701, and 46185801

DP#s: 322978 and 315780
Subject: Novaluron. Petitions for the Establishment of Permanent Tolerances for Use on *Brassica*, head and stem, subgroup 5A (PP#4E6834) and Label Amendment for New Use on Pome Fruit (PP#2F6430). Summary of Analytical Chemistry and Residue Data.
From: S. Levy
To: D. Kenny
Dated: 11/3/05
MRIDs: 46257301 and 46512101

F. DOCUMENT TRACKING

RDI: RAB1 Chemists (29-SEP-10)
Petition Number(s): 0E7723
DP Barcode(s): 378631
PC Code: 124002

Template Version June 2005.

Novaluron/PC Code 124002/Makhteshim-Agan of North America Inc.
DACO 7.8/OPPTS 860.1460
Food-Handling Establishments

Primary Evaluator	Julie L. Van Alstine, MPH, Environmental Health Scientist Risk Assessment Branch 1 (RAB1) Health Effects Division (HED; 7509P), US EPA	Date: 15-SEP-2011
Approved by	George F. Kramer, Ph.D., Senior Chemist RAB1/HED (7509P), US EPA	Date: 15-SEP-2011

Note: This data-evaluation record (DER) was originally prepared under contract by Versar, Inc. (6850 Versar Center, Springfield, VA 22151; submitted 09/24/10). The DER has been reviewed by HED and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID 48034901 Van Hoven, R., Nixon, W. (2009) Laboratory Validation of Methods for the Analysis of Novaluron in/on Butter, Processed Meat, Milk, White Bread, Lettuce, and Dinner Plate. Project ID: Wildlife International, Ltd. 234C-106. Unpublished study prepared by Wildlife International, Ltd. for Makhteshim-Agan of North America Inc. 70 p.

MRID 48034902 Van Hoven, R., Nixon, W., Schutt, W. (2009) Evaluation of the Freezer Storage Stability of Novaluron in/on Butter, Processed Meat, Milk, White Bread, Lettuce, and Dinner Plate. Project ID: Wildlife International, Ltd. 234C-107. Unpublished study prepared by Wildlife International, Ltd. for Makhteshim-Agan of North America Inc. 72 p.

MRID 48034903 Hummel, R. (2009) Residue in Food Commodities Following Application of a Liquid Formulation of Novaluron as a Space Spray Treatment in a Simulated Food Handling Establishment. Project ID: 14521A008. Unpublished study prepared by Landis International, Inc. for Makhteshim-Agan of North America Inc. 156 p.

EXECUTIVE SUMMARY:

A residue study was conducted for a simulated food-handling establishment by Landis International, Inc. A space spray treatment of Diamond® 0.83 EC, containing 0.83 lb ai/gal novaluron, in the form of a fine mist (i.e., fog) was made at an application rate of 38.75 mg ai/m^2 (target rate of 25 mg/m^2) which was stated to be 3X the label rate. The treated room contained three tables with randomly placed test matrices, including butter, sliced turkey meat, whole milk, sliced white bread, iceberg head lettuce, and bare plates. A subset of the matrices sampled was covered with thin plastic wrap to simulate typical storage conditions in a food handling establishment. Uncovered treated samples were collected at sampling intervals of 4, 8, and 12 hours post-application, while covered treated samples were collected at 4 and 12 hours. Additional uncovered samples were placed in the rooms 2 hours after the spray application and collected at the same time as the 4- and 12-hour samples to evaluate deposition due to test substance volatilization. An untreated room was established as a control in a separate building. Untreated samples were collected 1 hour prior to treatment and 12 hours post-treatment.

Novaluron residues were measured using liquid chromatography/mass spectroscopy/mass spectroscopy (LC/MS/MS) in the negative-ion multiple-reaction monitoring (MRM) mode. The limit of quantitation (LOQ) was 0.01 ppm for all food commodities and 0.02 µg for dinner plates. Limits of detection (LODs) were not reported.

The maximum storage interval from sampling to extraction was 49 days for samples of butter, 43 days for meat, 77 days for milk, 69 days for bread, 63 days for lettuce, and 82 days for dinner plates. All samples were analyzed within 4 days of extraction. The storage stability of novaluron has been demonstrated in/on butter, bread, and lettuce for up to 70 days; in meat for up to 71 days; in milk for up to 92 days; and in dinner plates for up to 92 days (MRID 48034902). Analysis of field fortified samples, stored for the same length of time as the field samples, indicates that residues of novaluron were stable during transport and storage.

Following a single treatment of novaluron at a rate of 38.75 mg ai/m^2, residues on uncovered sample matrices ranged from 0.140 to 1.12 ppm in/on butter (maximum at 4 hours); 0.0111 to 3.31 ppm in/on meat (maximum at 8 hours); 0.250 to 0.620 ppm in/on milk (maximum at 12 hours); 2.47 to 10.1 ppm in/on bread (maximum at 12 hours); 0.316 to 2.29 ppm in/on lettuce (maximum at 4 hours); and 784 to 1088 µg for dinner plates (maximum at 8 hours). For uncovered butter and lettuce, residue concentrations of novaluron decreased by the end of the sampling period, while concentrations in/on uncovered meat, milk, bread, and dinner plates increased slightly over time.

Residues for all covered food matrices samples were <LOQ (<0.010 ppm), except for one sample of bread collected 4 hours post-application (0.0142 ppm). Residues on covered dinner plates ranged from 0.318 to 1.51 µg with the maximum occurring at 4 hours post-application.

All volatilization food samples, placed in rooms 2 hours after the spray application, were <LOQ (<0.010 ppm). Dinner plates placed in the room at 2 hours post-application had measured novaluron residues ranging from 0.905 to 1.03 µg.

With the exception of one +12 hour replicate in the butter matrix (0.00176 ppm), novaluron was not detected in any of the control food or dinner plate samples.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the residue data are classified as scientifically acceptable.

The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, D378635.

COMPLIANCE:

Signed and dated Good Laboratory Practices (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an impact on the validity of the study.

A. BACKGROUND INFORMATION

Novaluron, *N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide, is a pesticide chemical belonging to the class of insecticides called insect-growth regulators (IGR). IGRs kill the insects over a period of a few days by disrupting the normal growth and development of immature insects. Novaluron acts as an insecticide mainly by ingestion, but has some contact activity.

The chemical structure and nomenclature of novaluron are presented in Table A.1., and the physicochemical properties are provided in A.2.

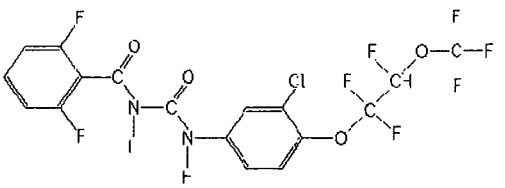
Table A.1. Novaluron Nomenclature.	
Compound	
Common name	Novaluron
Company experimental name	Not applicable.
IUPAC name	1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea
CAS name	*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]amino]carbonyl]-2,6-difluorobenzamide
CAS registry number	116714-46-6
End-use product (EP)	0.83 lb ai/gal - Diamond® 0.83 EC Insecticide (EPA Reg. No. 66222-35)

TABLE A.2. Physicochemical Properties of Novaluron.			
Parameter	Value		Reference
Melting range	176.5 – 178 °C		e-Pesticide Manual, Version 3.1 DP#s 322978 & 315780, 11/3/05, S. Levy
pH	6.5		
Specific gravity at 22 °C	1.56 g/cm^3		
Water solubility at 25 °C	3 µg/L		
Solvent solubility	Solvent	Solubility (g/L)	DP#s 322978 & 315780,

TABLE A.2. Physicochemical Properties of Novaluron.			
Parameter	Value		Reference
	n-heptane	8.39 (mg/L)	11/3/05, S. Levy
	xylene	1.88	
	1,2-dichloroethane	2.85	
	methanol	14.5	
	acetone	198.5	
	ethyl acetate	113.0	
	n-octanol	0.98	
Vapor pressure at 25 °C	1.6×10^{-5} Pa		
Dissociation constant (pK_a)	Not investigated due to the low water solubility of the test material.		
Octanol/water partition coefficient Log(K_{OW}) at 25 °C	$\log K_{ow} = 4.3$		
UV/visible absorption spectrum	$\lambda_{max} = 253$ nm		

B. EXPERIMENTAL DESIGN

The study protocol (MRID 47528201) was reviewed by HED prior to the start of the study (Memo, J. Langsdale, 18-NOV-2008; D356505). The study utilized one treated and one untreated room housed in different buildings. According to the study report, the rooms simulated commercial food service, handling, processing, and manufacturing areas. Plates, saucers, and glasses (for milk) were obtained from a commercial restaurant supplier and were washed with Cascade® dishwashing gel and dried in a standard household dishwasher prior to use in the study.

Covered and uncovered samples of commercially available foods (butter, turkey meat, milk, lettuce, and bread) and bare plates were randomly placed on tables approximately 3 feet off the floor. Novaluron was then applied to the room in a single treatment as a fogger, simulating a routine pest control treatment. The applicator walked through the room in a pre-determined pattern using a fogging machine (Fogmaster Jr.) to distribute a fine mist (fog) throughout the top 1/3 volume of the room. The target rate was 25 mg ai/m^2; however, the actual application rate was 38.75 mg ai/m^2. According to the study report, the fogging machine dispensed approximately 55% more test solution than planned (i.e., during calibration the machine delivered approximately 50 mL/minute, but during the application the machine delivered approximately 75 mL/minute). It was stated that there was no obvious sign of a malfunction with the equipment, and that all data indicated that the test solution was distributed evenly within each portion of the treated room. Two water-sensitive cards were placed randomly within each replicate area and confirmed a spray pattern consistent with fine mist/fog in each portion of the treated room. Prior to and during the application, the air handling unit was turned off and was turned back on approximately 2 hours following the application and set to maintain a reasonable "room temperature" range. Following the application, all doors and windows were closed. The door was only opened when workers entered the room to collect samples.

Uncovered treated samples were collected at sampling intervals of 4, 8, and 12 hours post-application, while covered treated samples were collected at 4 and 12 hours. Additional uncovered samples were placed in the rooms 2 hours after the spray application and collected at the same time as the 4- and 12-hour samples to evaluate deposition due to test substance volatilization. Untreated samples were collected 1 hour prior to treatment and 12 hours post-

treatment.

B.1. Study Site Information

TABLE B.1.1. Study Site and Use Pattern.

Establishment identification	Establishment Type	EP[1]	Application					Residue-transfer Route
			Method	Rate	Retreat. Interval (Days)	No. of Applics.	Coapplied Adjuvants	
Landis International, Ltd.	Simulated Food-Handling Establishment (rooms)	0.83 lb ai/gal EC	Space treatment (fogger)	38.75 mg ai/m^2	NA	1	Not specified	Air

[1]EP = end-use product.

B.2. Sample Handling and Preparation

After collection, both non-treated and treated samples were wrapped, placed into labeled bags, and frozen prior to shipment to the analytical laboratory. For each matrix, triplicate control samples were fortified at two levels (0.10 ppm and 0.20 ppm) to assess the stability of residues in each matrix during shipment to the analytical facility. The fortified samples were stored, and shipped at the same time as the collected samples.

Samples were stored for 15 to 16 days at the field study location and then transported to the analytical laboratory via ACDS Freezer truck. Food matrices were homogenized at the analytical laboratory and all samples were stored frozen (-18 °C) until extraction and analysis.

B.3. Analytical Methodology

Samples were analyzed based on the analytical methodology described in Protocol Amendment 1A to Landis International, Inc. Protocol Number 14521A008, entitled "Residue in Food Commodities Following Application of a Liquid Formulation of Novaluron as a Space Spray Treatment in a Simulated Food Handling Establishment." The methods have not been reviewed by the EPA; however, the methods were based on previous food methodologies used to analyze residues of novaluron. Additionally, an acceptable study report entitled "Laboratory Validation of Methods for the Analysis of Novaluron in/on Butter, Processed Meat, Milk, White Bread, Lettuce, and Dinner Plate" (MRID 48034901) was submitted which validates the method.

Homogenized food matrices, except lettuce, were extracted with acetonitrile (3 x 20 mL), cleaned up with hexane partitions (2 x 50 mL), concentrated using rotary evaporation with nitrogen, reconstituted in acetone with the aid of sonification, and filtered through a 0.45-µm polytetrafluoroethylene (PTFE) filter. Lettuce was first treated with methanol extraction (20 mL) followed by acetonitrile extractions (2 x 20 mL) and the clean up, concentration and filtration steps described for the other food matrices. Aliquots of the filtered extracts were diluted with a solution of 50:50:0.1 (v/v/v) MeOH:H_2O:formic acid. For the dinner plates, the entire upper or eating surface was extracted using three washes of 10 mL acetone which were

combined in a flask, evaporated, reconstituted, and diluted in the same manner as the food matrices less the filtration step. Residues were measured using LC/MS/MS in the negative-ion MRM mode. The LOQ was 0.01 ppm for all food commodities and 0.02 µg for dinner plates. LODs were not reported. The same method was used to analyze samples in the freezer storage stability study (MRID 48034902).

In conjunction with the food-handling trial, the method was concurrently validated using control samples of butter fortified with novaluron at 0.010-2.0 ppm; turkey meat fortified at 0.010-3.5 ppm; milk fortified at 0.010-1.0 ppm; bread fortified at 0.010-15.0 ppm; lettuce fortified at 0.010-3.0 ppm; and dinner plates fortified at 0.020-1200 µg.

C. RESULTS AND DISCUSSION

Sample storage conditions and intervals are summarized in Table C.2.1. The maximum storage interval from sampling to extraction was 49 days for samples of butter, 43 days for meat, 77 days for milk, 69 days for bread, 63 days for lettuce, and 82 days for dinner plates. All samples were analyzed within 4 days of extraction. Samples which were fortified at the treatment facility (field fortified samples) were stored for the same length of time as the field samples and indicate that residues of novaluron were stable during transport and storage (Table C.2.2). Mean recoveries ranged from 80% to 112%. An acceptable storage stability study has also been submitted which demonstrates the storage stability of novaluron in/on butter, bread, and lettuce for up to 70 days; in meat for up to 71 days; in milk for up to 92 days; and in/on dinner plates for up to 92 days (Table C.2.3; MRID 48034902). Sample sets for each storage interval consisted of two stored fortified samples and three control (untreated) samples with two controls fortified just prior to extraction to evaluate concurrent recovery. Corrected recoveries ranged from 85% to 111%.

Concurrent method recovery data are shown in Table C.1. The method was adequate for data collection based on concurrent method recoveries and the submitted method validation study (MRID 48034901). Control samples were fortified with novaluron at concentrations ranging from 0.010 to 15.0 ppm for food matrices and 0.020-1200 µg for dinner plates. All recoveries but one (133% recovery for dinner plates fortified at 0.020 µg) were between the acceptable range of 70-120% and all mean recoveries were within the acceptable range. Residues in controls were <LOQ.

Residue data from the study trial are reported in Table C.3. A summary of the residue data is presented in Table C.4.

Following a single treatment of novaluron at a rate of 38.75 mg ai/m^2, residues on uncovered sample matrices ranged from 0.140 to 1.12 ppm in/on butter (maximum at 4 hours); 0.0111 to 3.31 ppm in/on meat (maximum at 8 hours); 0.250 to 0.620 ppm in/on milk (maximum at 12 hours); 2.47 to 10.1 ppm in/on bread (12 hours); 0.316 to 2.29 ppm in/on lettuce (maximum at 4 hours); and 784 to 1088 µg (0.784 to 1.088 mg/plate) for dinner plates (maximum at 8 hours). For uncovered butter and lettuce, residue concentrations of novaluron decreased by the end of

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the sampling period, while concentrations in/on uncovered meat, milk, bread, and dinner plates increased slightly over time.

Residues for all covered food matrices samples were <LOQ (<0.010 ppm), except for one sample of bread collected 4 hours post-application (0.0142 ppm). Residues on covered dinner plates ranged from 0.318 to 1.51 µg (0.000318 to 0.00151 mg/plate) with the maximum occurring at 4 hours post-application.

All volatilization food samples, placed in rooms 2 hours after the spray application, were <LOQ (<0.010 ppm). Dinner plates placed in the room at 2 hours post-application had measured novaluron residues ranging from 0.905 to 1.03 µg.

According to OPPTS 860.1460, space spray application is the most rigorous type of treatment and a worst-case application scenario may be sufficient to cover all types of establishments. Although measured residues for covered samples were generally below the LOQ, one sample of bread (4 hours post-application) and all samples from dinner plates covered with plastic wrap had detectable levels of novaluron. The residues on the covered plates were approximately 1000 times less than those on uncovered plates.

TABLE C.1. Summary of Concurrent Recoveries of Novaluron from Various Matrices.

Matrix	Spike level	Sample size (n)	Recoveries (%)	Mean ± std dev[1] (%)
Butter	0.0100 ppm	2	101, 93	97
	0.100 ppm	3	99, 89, 95	94 ± 5.0
	0.200 ppm	2	104, 91	98
	2.0 ppm	1	104	--
Turkey, meat	0.0100 ppm	2	81, 90	86
	0.100 ppm	3	98, 98, 92	96 ± 3.5
	0.200 ppm	3	99, 103, 99	100 ± 2.3
	3.5 ppm	1	102	--
Milk	0.0100 ppm	2	94, 95	94
	0.100 ppm	3	98, 95, 92	95 ± 3.0
	0.200 ppm	2	102, 90	96
	1.0 ppm	1	89	--
Bread	0.0100 ppm	2	99, 93	96
	0.100 ppm	3	111, 92, 101	101 ± 9.5
	0.200 ppm	2	94, 92	93
	15.0 ppm	1	95	--
Lettuce	0.0100 ppm	2	73, 80	77
	0.100 ppm	3	87, 92, 88	89 ± 2.6
	0.200 ppm	2	84, 94	89
	2.0 ppm	1	94	--
	3.0 ppm	1	96	--
Dinner plates	0.020 µg	2	133, 107	120

TABLE C.1. Summary of Concurrent Recoveries of Novaluron from Various Matrices.

Matrix	Spike level	Sample size (n)	Recoveries (%)	Mean ± std dev[1] (%)
	0.200 µg	3	117, 118, 110	115 ± 4.4
	0.400 µg	2	109, 107	108
	1200 µg	1	117	--

[1] Standard deviation is only calculated for sample sizes ≥3.

TABLE C.2.1. Summary of Storage Conditions.

Matrix (Description)	Storage Temperature (°C)[1]	Actual Storage Duration (days or months)[2]	Interval of Demonstrated Storage Stability (days or months)[3]
Butter (Salted sweet cream butter)	-18	49 days (1.6 months)	70 days (2.3 months)
Meat (Roasted white turkey meat)		43 days (1.4 months)	71 days (2.3 months)
Milk (Vitamin D whole milk)		77 days (2.5 months)	92 days (3.0 months)
Bread (Whitewheat® bread)		69 days (2.3 months)	70 days (2.3 months)
Lettuce (Iceberg head lettuce)		63 days (2.1 months)	70 days (2.3 months)
Dinner plates (Glazed, vitreous china plate)		82 days (2.7 months)	92 days (3.0 months)

[1] Storage temperatures at the analytical facility. Samples were stored in the field at -21 to 15 °F.
[2] Elapsed days from sampling to extraction. All samples were analyzed within 4 days of extraction.
[3] Wildlife International Study 234C-107 (MRID 48034902).

TABLE C.2.2. Summary of Field Fortification Recoveries of Novaluron from Various Matrices.

Matrix	Storage Interval[1] (days)	Spike level	Sample size (n)	Recoveries (%)	Mean ± std dev[2] (%)
Butter	49	0.100 ppm	3	81, 92, 90	88±5.9
		0.200 ppm	3	91, 99, 95	95±4.0
Turkey, meat	46	0.100 ppm	3	92, 88, 87	89±2.6
		0.200 ppm	3	104, 103, 102	103±1.0
Milk	77	0.100 ppm	3	88, 84, 87	87±2.1
		0.200 ppm	2	98, 101	100
Bread	69	0.100 ppm	3	75, 80, 85	80±5.0
		0.200 ppm	3	92, 86, 88	89±3.1
Lettuce	63	0.100 ppm	3	62, 154, 75	97±50
		0.200 ppm	3	94, 92, 101	96±4.7
Dinner plates	82	0.200 µg	3	92, 106, 107	102±8.4
		0.400 µg	3	115, 105, 116	112±6.1

[1] Elapsed days from preparation to extraction. All samples were analyzed within 7 days of extraction.
[2] Standard deviation is only calculated for sample sizes ≥3.

TABLE C.2.3. Stability of Novaluron Residues in/on Butter, Meat, Milk, Bread, Lettuce, and Dinner Plates Following Storage at -18.6 ± 0.6 °C.[1]

Commodity	Spike Level (ppm)[2]	Storage Interval (days)	Freshly Fortified Recovery ppm (Average %)	Recovered Residues ppm (%)	Corrected Recovery[3] (%)
Butter	0.100	32	0.0952, 0.0962 (95.7)	0.0937 (93.7), 0.100 (100)	97.9, 104
		70	0.0953, 0.0970 (96.2)	0.0996 (99.6), 0.103 (103)	104, 107
Turkey, meat	0.100	33	0.124, 0.120 (122)	0.117 (117), 0.122 (122)	95.9, 100
		71	0.108, 0.113 (110)	0.108 (108), 0.108 (108)	97.7, 97.7
Milk	0.100	30	0.0911, 0.0921 (91.6)	--[4], 0.0937 (93.7)	--[4], 102
		92	0.106, 0.105 (106)	0.106 (106), 0.104 (104)	100, 98.6
Bread	0.100	30	0.0912, 0.0896 (90.4)	0.0789 (78.9), 0.0816 (81.6)	87.3, 90.3
		70	0.106, 0.104 (105)	0.0999 (99.9), 0.0971 (97.1)	95.1, 92.5
Lettuce	0.100	30	0.0878, 0.0858 (86.8)	0.0964 (96.4), 0.0939 (93.9)	111, 108
		70	0.0941, 0.0952 (94.6)	0.0808 (80.8), 0.104 (104)	85.4, 110
Dinner plates	0.200 µg	23	0.208, 0.206 (104)	0.215 (108), 0.214 (107)	104, 103
		92	0.242, 0.232 (118)	0.239 (120), 0.234 (117)	101, 98.7

[1] As reported in MRID 48034902.
[2] The units for food matrices are ppm and the units for dinner plates are µg.
[3] Corrected for concurrent method recovery using the average of the freshly fortified recovery data.
[4] According to the study report, the sample was compromised upon processing.

TABLE C.3. Residue Data from Food Handling Establishment Residue Studies with Novaluron.

Establishment Name and Type	Commodity[1]	Total Rate mg ai/m^2	Method/Transfer Route	Novaluron Residues (ppm)[2]
Simulated Food-Handling Establishment: High-Rate Room	Butter, 4-hr, uncovered (VOL)	38.75	Air	<LOQ <LOQ <LOQ
	Butter, 4-hr, uncovered		Air	1.12 0.641 0.861
	Butter, 8-hr, uncovered		Air	0.716 0.970 0.979
	Butter, 12-hr, uncovered		Air	0.392 0.140 0.603
	Butter, 4-hr, covered		Air	<LOQ <LOQ <LOQ
	Butter, 12-hr, covered		Air	<LOQ <LOQ <LOQ
Simulated Food-Handling Establishment: High-Rate Room	Meat, 4-hr, uncovered (VOL)	38.75	Air	<LOQ <LOQ <LOQ
	Meat, 4-hr, uncovered		Air	1.58 2.50 0.0111

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TABLE C.3. Residue Data from Food Handling Establishment Residue Studies with Novaluron.

Establishment Name and Type	Commodity[1]	Total Rate mg ai/m^2	Method/Transfer Route	Novaluron Residues (ppm)[2]
	Meat, 8-hr, uncovered		Air	3.31 2.96 2.29
	Meat, 12-hr, uncovered		Air	2.24 2.54 1.38
	Meat, 4-hr, covered		Air	<LOQ <LOQ <LOQ
	Meat, 12-hr, covered		Air	<LOQ <LOQ <LOQ
Simulated Food-Handling Establishment: High-Rate Room	Milk, 4-hr, uncovered (VOL)	38.75	Air	<LOQ <LOQ <LOQ
	Milk, 4-hr, uncovered		Air	0.453 0.343 0.320
	Milk, 8-hr, uncovered		Air	0.272 0.611 0.340
	Milk, 12-hr, uncovered		Air	0.620 0.250 0.365
	Milk, 4-hr, covered		Air	<LOQ <LOQ <LOQ
	Milk, 12-hr, covered		Air	<LOQ <LOQ <LOQ
Simulated Food-Handling Establishment: High-Rate Room	Bread, 4-hr, uncovered (VOL)	38.75	Air	<LOQ <LOQ <LOQ
	Bread, 4-hr, uncovered		Air	2.57 4.06 3.27
	Bread, 8-hr, uncovered		Air	3.45 4.49 4.08
	Bread, 12-hr, uncovered		Air	10.1 4.31 2.47
	Bread, 4-hr, covered		Air	<LOQ <LOQ 0.0142

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TABLE C.3. Residue Data from Food Handling Establishment Residue Studies with Novaluron.

Establishment Name and Type	Commodity[1]	Total Rate mg ai/m^2	Method/Transfer Route	Novaluron Residues (ppm)[2]
	Bread, 12-hr, covered		Air	<LOQ <LOQ <LOQ
Simulated Food-Handling Establishment: High-Rate Room	Lettuce, 4-hr, uncovered (VOL)	38.75	Air	<LOQ <LOQ <LOQ
	Lettuce, 4-hr, uncovered		Air	2.29 1.39 1.67
	Lettuce, 8-hr, uncovered		Air	1.42 2.16 1.38
	Lettuce, 12-hr, uncovered		Air	1.92 0.316 1.67
	Lettuce, 4-hr, covered		Air	<LOQ <LOQ <LOQ
	Lettuce, 12-hr, covered		Air	<LOQ <LOQ <LOQ
Simulated Food-Handling Establishment: High-Rate Room	Dinner plates, 4-hr, uncovered (VOL)	38.75	Air	0.920 µg 0.905 µg 1.03 µg
	Dinner plates, 4-hr, uncovered		Air	870 µg 856 µg 1004 µg
	Dinner plates, 8-hr, uncovered		Air	1088 µg 784 µg 882 µg
	Dinner plates, 12-hr, uncovered		Air	921 µg 1072 µg 1074 µg
	Dinner plates, 4-hr, covered		Air	1.51 µg 0.494 µg 0.665 µg
	Dinner plates, 12-hr, covered		Air	0.318 µg 0.790 µg 0.490 µg

[1] Samples designated with "VOL" were placed in the room 2 hours following the spray application. These samples were designed to evaluate deposition due to test substance volatilization.

[2] ND = nondetectable. The method LOQ for food matrices is 0.01 ppm and 0.02 µg for dinner plates. The units for food matrices are ppm and the units for dinner plates are µg.

TABLE C.4. Summary of Residue Data from Food-Handling Establishment Studies with Novaluron.

Commodity	Total Applic. Rate mg ai/m^2	Method/ Transfer Route	Residue Levels[1] (ppm)						
			n	Min.	Max.	HAFT[2]	Median	Mean	Std. Dev.
Butter, uncovered	38.75	Air	9	0.140	1.12	0.888	0.716	0.714	0.311
Butter, covered			6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Meat, uncovered	38.75	Air	9	0.0111	3.31	2.85	2.29	2.09	0.985
Meat, covered			6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Milk, uncovered	38.75	Air	9	0.250	0.620	0.412	0.343	0.397	0.136
Milk, covered			6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Bread, uncovered	38.75	Air	9	2.47	10.10	5.63	4.06	4.31	2.29
Bread, covered			6	<LOQ	0.0142	0.0114	0.0100	0.0107	0.00171
Lettuce, uncovered	38.75	Air	9	0.316	2.29	1.78	1.67	1.58	0.578
Lettuce, covered			6	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Dinner plates, uncovered	38.75	Air	9	784 µg	1088 µg	1022 µg	921 µg	950 µg	112 µg
Dinner plates, covered			6	0.318 µg	1.51 µg	0.890 µg	0.580 µg	0.711 µg	0.424 µg

[1] The LOQ is 0.01 ppm for all food matrices and 0.02 µg for dinner plates. For the median, mean, and standard deviation, the LOQ was used for residues reported below the LOQ in Table C.3.1. The units for food matrices are ppm and the units for dinner plates are µg.
[2] HAFT = highest-average field trial.

D. CONCLUSION

The food-handling study is adequate and reflects the use of novaluron as a space spray treatment to a simulated commercial food establishment at a rate of 38.75 mg ai/m^2. Uncovered treated samples were collected at sampling intervals of 4, 8, and 12 hours post-application, while covered treated samples were collected at 4 and 12 hours. Additional uncovered samples were placed in the rooms 2 hours after the spray application to evaluate deposition due to test substance volatilization. Samples were stored frozen for up to 82 days. Acceptable storage stability data are available to support the storage durations and conditions of sampled matrices (MRID 48034902).

Based on concurrent recoveries, an acceptable method was used for quantitation of residues in/on food matrices and dinner plates. Additionally, an acceptable study report was submitted which validates the method (MRID 48034901). Residues were detected on uncovered food matrices and dinner plates up to 12 hours after novaluron application at a worst case rate of 38.75 mg

ai/m^2. Maximum residues on uncovered sample matrices were 1.12 ppm in/on butter (4 hours post-application); 3.31 ppm in/on meat (8 hours post-application); 0.620 ppm in/on milk (12 hours post-application); 10.1 ppm in/on bread (12 hours post-application); 2.29 ppm in/on lettuce (4 hours post-application); and 1088 µg for dinner plates (8 hours post-application). For uncovered butter and lettuce, residue concentrations of novaluron decreased by the end of the sampling period, while concentrations in/on uncovered meat, milk, bread, and dinner plates increased slightly over time.

Although measured residues for covered samples were generally below the LOQ, one sample of bread (4 hours post-application) and all samples from dinner plates covered with plastic wrap had detectable levels of novaluron. The residues on the covered plates were approximately 1000 times less than those on uncovered plates.

All volatilization food samples, placed in rooms 2 hours after the spray application, were <LOQ (<0.010 ppm). Dinner plates placed in the room at 2 hours post-application had measured novaluron residues ranging from 0.905 to 1.03 µg.

E. REFERENCES

DP#: 356505
Subject: Review of Protocol for use of Novaluron (Rimon® 0.83EC Insecticide; EPA Reg. No. 66222-35) in Food/Feed Areas of Food-Handling Establishments.
From: J. M. Langsdale
To: K. Davis/V. Eagle
Date: 11/18/2008
MRID#s: 47528200; 47528201

F. DOCUMENT TRACKING

RDI: RAB1 Chemists (10-NOV-10)
Petition Number(s): 0F7708
DP Barcode(s): 378635
PC Code: 124002

13544

R194677

Chemical Name: Novaluron

PC Code: 124002
HED File Code: 11000 Chemistry Reviews
Memo Date: 9/15/2011
File ID: 00000000
Accession #: 000-00-0137

HED Records Reference Center
9/20/2011